



# The Structure of Whole Quality

## From Quality Objects to Factors, Indicators, and Outcomes

### Foundational Article 1

#### Whole-Quality Institute

Quality is often discussed as if it begins with indicators, measurements, checklists, or performance scores. But this can create confusion. A measurement may be useful only when it is clear what object is being evaluated, what quality state is being described, what functions or results are expected, and what evidence supports the claim.

Whole-Quality begins from a different starting point:

#### **Quality begins with the Quality Object.**

From that object, Whole-Quality identifies the essential details that form the quality state: boundaries, interfaces, intended functions, intended results, failure-mode families, Quality Factors, Indicators, Quality Outcome Criteria, Evidence, and the Reference Layer.

This sequence is important because it prevents quality from becoming a list of disconnected expectations. It helps make quality visible by showing how each part of the method is derived from what the object is, what it is expected to do or produce, and how quality can be achieved, weakened, lost, or evidenced.

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## 1. The Whole-Quality Method

The Whole-Quality method is a tool for making quality visible. It helps us look at an object as a whole and understand its quality state through the essential details that form it.

**Quality Object → Boundaries → Interfaces → Intended Functions and Intended Results → Failure-Mode Families → Quality Factors → Indicators → Quality Outcome Criteria → Evidence → Reference Layer**

This sequence helps connect what the object is, what matters for its quality, what should be observed, what result is expected, what evidence exists, and what quality claim can be made.

A Quality Factor should not be selected simply because it sounds important. It should be derived from the object being evaluated, its boundaries, its interfaces, its intended functions and results, and the main ways quality can be achieved, weakened, or lost.

An Indicator should not be chosen first. It should be derived from a Quality Factor.

Quality Outcome Criteria should not be isolated targets. They should describe what condition or result must be achieved, avoided, maintained, controlled, or evidenced under a defined Indicator.

Evidence should not be generic paperwork. It should support a specific quality claim about whether the relevant Outcome Criteria are met, not met, uncertain, or insufficiently evidenced.

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## 2. Quality Object

The first question is:

**What is the object whose quality is being evaluated?**

This question is foundational.

For example:

- In support services, the object may be the actual support service experienced by the person.
- In infrastructure, the object may be an infrastructure asset or system-of-systems throughout its lifecycle.
- In product quality, the object may be the product as a functioning object, including materials, components, interfaces, use conditions, and evidence.
- In quality management, the object may be the management system itself.
- In human health, the object may be the whole human body-mind-person system.

Different objects require different Quality Factors. The quality of a bridge, a personal care service, a product, a quality management system, and a human health condition cannot be evaluated by the same checklist.

But the method for deriving the structure of quality can be the same.

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## 3. Boundaries

Once the quality object is defined, its boundaries must be identified.

A **boundary** is the stated separation between two sides of a quality interpretation.

A boundary determines what is inside the quality claim and what is outside it.

A boundary may be:

- physical;
- functional;
- organizational;
- lifecycle-based;
- regulatory;
- operational;
- technical;
- environmental;
- social;
- informational;
- evidence-based;
- or related to responsibility, condition, or claim scope.

A boundary may separate the quality object from its external environment. It may also separate one subsystem, function, process, lifecycle stage, or responsibility area from another inside the quality object.

Without boundaries, quality claims become vague. A claim may sound broad and positive, but it may not be clear what was actually evaluated.

For Whole-Quality purposes, a quality claim must be linked to a defined object and a defined boundary.

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## 4. Boundaries and Interfaces

After boundaries are identified, the next question is:

### **Where do quality-relevant interactions occur?**

An **interface** is the quality-relevant interaction condition between the two sides of a boundary.

In simple terms:

**Boundary = the stated separation between two sides.**

**Interface = the quality-relevant interaction condition between those two sides.**

An interface may exist **at**, **across**, or **within** a boundary.

Interfaces may be external or internal.

## **External interfaces**

External interfaces occur where the quality object interacts with something outside itself.

Examples include:

- service ↔ person;
- infrastructure ↔ environment;
- organization ↔ supplier;
- management system ↔ customer;
- body/person ↔ care environment;
- system ↔ regulator;
- asset ↔ community;
- provider ↔ funder;
- technology ↔ user.

External interfaces matter because the quality object may depend on conditions, responsibilities, information, risks, or effects that arise outside its internal structure.

## **Internal interfaces**

Internal interfaces occur inside the quality object, where subsystems, functions, processes, responsibilities, or lifecycle stages interact with each other.

Examples include:

- subsystem ↔ subsystem;
- function ↔ function;
- process ↔ process;

- department ↔ department;
- lifecycle stage ↔ lifecycle stage;
- body system ↔ body system;
- mental condition ↔ physical condition;
- monitoring system ↔ decision-making process;
- evidence source ↔ quality claim.

Internal interfaces matter because whole quality can fail even when individual parts appear acceptable. The failure may occur between parts, not only inside one part.

## **Example: human health**

In a human-health quality object, the human being is treated as a whole living body-mind-person system.

But this whole object contains many internal subsystem boundaries and interfaces.

For example:

- skeleton ↔ muscles;
- muscles ↔ nerves;
- brain ↔ body;
- cardiovascular system ↔ respiratory system;
- digestive system ↔ metabolism;
- endocrine system ↔ reproductive system;
- immune system ↔ inflammation;
- mental state ↔ physical function;
- medication ↔ body systems;
- body ↔ environment.

These are not merely separate parts. They are interaction conditions.

For example, the boundary may distinguish the musculoskeletal system from the nervous system. The interface is the interaction condition between muscles, skeleton, nerves, coordination, sensation, movement, balance, pain, and functional ability.

Whole-person health quality depends not only on the condition of each subsystem, but also on the quality-relevant interactions among them.

## **Example: natural gas main pipeline transportation infrastructure**

In IQI Context Guide MNT1 — Natural Gas Main Pipeline Transportation Infrastructure, natural gas main pipeline transportation infrastructure is treated as an integrated system-of-systems, not as an isolated pipe segment.

Its quality depends on the behavior and interaction of pipeline sections, compressor stations, pressure-control systems, cathodic protection, communication and telemetry, SCADA, monitoring, emergency-protection systems, transported-medium conditions, environmental and geotechnical conditions, lifecycle transitions, and public-consequence interfaces.

This shows why Whole-Quality analysis must define both the quality object and the boundaries and interfaces that shape its behavior and quality claims.

## Example: quality management system

In a quality management system, boundaries may distinguish:

- one process from another process;
- one department from another department;
- customer-facing processes from internal support processes;
- leadership responsibility from operational responsibility;
- supplier control from internal production or service delivery;
- documented information from actual process performance;
- corrective action from improvement planning.

The interface is the handoff or interaction condition between these sides.

For example, one process may produce information needed by another process. If that information is incomplete, late, unclear, or not used, the management system may fail even if both processes appear separately defined.

For this reason, a management system must be evaluated not only by its documented processes, but also by the interaction conditions among those processes.

## Why interfaces matter

Interfaces matter because many serious quality failures occur not only inside a component, subsystem, or organization, but **between** subsystems, responsibilities, stages, environments, or information flows.

Whole Quality therefore requires attention to:

- the quality object as a whole;
- its external boundaries and interfaces;
- its internal subsystem boundaries and interfaces;
- the interaction conditions that affect function, safety, continuity, evidence, and quality-claim validity.

# 5. Intended Functions and Intended Results

The next question is:

**What is this object intended to do, and what results is it expected to produce, preserve, or support?**

A quality object exists to realize certain intended functions and intended results.

These functions and results may come from many sources, including:

- the nature and purpose of the object;
- the needs of people who depend on it;
- stakeholder expectations;
- professional knowledge;
- laws and regulations;
- safety requirements;
- commercial agreements;
- social obligations;
- technical requirements;
- environmental conditions;
- and the physical, biological, or organizational realities that govern how the object can function.

A support service must support a person's daily life, dignity, safety, participation, and stability.

An infrastructure system must deliver intended functions safely, reliably, and compatibly with connected systems and environments.

A management system must help an organization consistently meet requirements, control processes, evaluate performance, correct failures, and improve.

A human health system must sustain life, function, adaptation, cognition, physical and mental stability, and participation in daily life.

Quality Factors must be connected to these intended functions and intended results. If a proposed factor does not relate to the object's function, result, failure modes, boundaries, interfaces, or claim validity, it may be secondary, misplaced, or merely descriptive.

## 6. Failure-Mode Families

After intended functions and intended results are identified, Whole-Quality analysis asks:

**What kinds of failure would make the quality of this object unacceptable, unstable, unsafe, ineffective, or unsupported by evidence?**

This does not always require listing every possible failure.

In complex fields, such as human health, the possible failure modes are enormous. They may include medical, psychiatric, disability, functional, environmental, medication-related, and social pathways.

In such cases, WQI groups failures into **failure-mode families**.

For example:

- functional decline failures;
- safety failures;
- interface failures;
- coordination failures;
- evidence failures;
- adaptation failures;
- technical-control failures;
- environmental-fit failures;
- corrective-action failures;
- continuity failures;
- monitoring and response failures.

This step is essential because Quality Factors should not be arbitrary. A Quality Factor exists because a meaningful category of quality must be controlled, supported, preserved, recognized, or evidenced.

However, not every failure-mode family automatically becomes a separate Quality Factor. Some may be expressed through Indicators, Quality Outcome Criteria, boundary and interface interpretation, evidence expectations, or the Reference Layer.

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## 7. Quality Factors

A **Quality Factor** is a broad dimension of quality derived from the object being evaluated, its boundaries, interfaces, intended functions, intended results, and failure-mode families.

Quality Factors organize what matters before Indicators and Outcome Criteria are defined.

Quality Factors are derived from:

- the quality object;
- its boundaries;
- its interfaces;
- its intended functions;
- its intended results;
- and its failure-mode families.

They are not merely topics. They are structural dimensions of quality.

A Quality Factor should be selected only when it represents a major, stable dimension of quality for the defined quality object.

Some important quality-relevant conditions may not need to appear as separate Quality Factors. They may instead be expressed through Indicators, Quality Outcome Criteria, boundary and interface interpretation, evidence expectations, or the Reference Layer.

For example, poor coordination, weak communication, unclear responsibility transfer, incomplete evidence, or uncontrolled interfaces may all seriously affect quality. But this does not mean that each must automatically become a standalone Quality Factor. The question is where each condition belongs in the quality structure.

Whole-Quality analysis therefore distinguishes between:

- **Quality Factors** — broad dimensions of quality;
- **Indicators** — observable aspects of a Quality Factor;
- **Quality Outcome Criteria** — defined conditions or results that must be met;
- **Evidence** — information supporting whether Outcome Criteria are met, not met, uncertain, or insufficiently evidenced;
- **Boundary and Interface interpretation** — clarification of where quality-relevant interactions occur;
- **Reference Layer** — external standards, guides, classifications, or professional knowledge needed for responsible evaluation.

For example:

If poor coordination can seriously affect the quality object, then coordination must be visible somewhere in the quality structure — for example through Indicators, Quality

Outcome Criteria, interface interpretation, responsibility definition, communication expectations, traceability, or evidence expectations. It does not necessarily need to become a separate Quality Factor.

If loss of documentation, traceability, or information continuity prevents the object's condition, behavior, responsibility, or history from being understood, then Documentation and Traceability may need to appear as a Quality Factor where appropriate.

If failure of interface control can create harm, loss of function, instability, or invalid quality claims, then interface control must be visible in the quality structure. It may appear through boundary interpretation, interface interpretation, Indicators, Quality Outcome Criteria, or context-specific interpretation rather than always as a standalone Quality Factor.

Evidence itself should not be confused with a Quality Factor. Evidence supports the determination of whether Quality Outcome Criteria are met, not met, uncertain, or insufficiently evidenced.

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## 8. Indicators

An **Indicator** is a specific observable aspect of a Quality Factor that shows where quality should be examined, monitored, or evaluated.

Indicators translate broad Quality Factors into practical points of observation.

They identify what must be looked at, while Outcome Criteria define what condition or result must be met.

Indicators are not chosen first. They are derived from Quality Factors.

One Quality Factor may have several Indicators because one broad quality dimension may need to be observed through several different aspects, signals, conditions, behaviors, records, events, patterns, or interactions.

For each Quality Factor, the question becomes:

**What observable condition, behavior, record, event, pattern, interaction, or absence of control would show whether this factor is working, weak, failing, or improving?**

For example:

- Under a corrective-action factor, indicators may include nonconformity recording, cause analysis, action tracking, and recurrence review.
- Under a mobility and injury-prevention factor, indicators may include falls, near-falls, transfer difficulty, balance change, and environmental hazards.
- Under an infrastructure interface factor, indicators may include boundary controls, third-party activity controls, environmental assumptions, protective zones, monitoring visibility, and inspection evidence.
- Under a management-system process factor, indicators may include process ownership, handoff control, acceptance criteria, feedback loops, and evidence of process interaction.

Indicators make Quality Factors observable.

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## 9. Quality Outcome Criteria

A **Quality Outcome Criterion** is a defined condition or result that must be met for an Indicator to be satisfied.

Outcome Criteria connect what is observed to what is acceptable, sufficient, or intended for the object, function, or result being evaluated.

Quality Outcome Criteria make Indicators evaluable.

One Indicator may have several Quality Outcome Criteria because a single Indicator may involve different dimensions of quality performance, risk control, continuity, evidence, user effect, system behavior, or claim validity.

The relationship is therefore:

**Quality Factor → multiple Indicators → multiple Quality Outcome Criteria → supporting Evidence**

For each Indicator, the question becomes:

**What conditions or results must be achieved, avoided, maintained, controlled, or evidenced in order to determine whether this Indicator supports the intended quality condition?**

### Example: management system

A management-system Indicator may be:

**Nonconformities are recorded and investigated.**

Related Quality Outcome Criteria may include:

- significant nonconformities are documented in a traceable manner;
- immediate correction is taken where needed to control the nonconforming condition;
- causes are analyzed at a level appropriate to the significance of the nonconformity;
- corrective actions are assigned, implemented, and reviewed;
- recurrence is monitored;
- lessons learned are used to improve the management system where appropriate.

## **Example: human health**

A human-health Indicator may be:

**Falls, near-falls, transfer difficulty, and balance changes are observed and communicated.**

Related Quality Outcome Criteria may include:

- changes in mobility or balance are recognized in a timely manner;
- fall or near-fall events are documented and communicated to the appropriate responsible party;
- environmental hazards contributing to fall risk are identified where relevant;
- support, care, or clinical pathways are adjusted when increased risk is identified;
- preventable injury risk is reduced through appropriate response;
- evidence is sufficient to determine whether fall-risk concerns were addressed or remain unresolved.

## **Example: pipeline transportation infrastructure**

A pipeline-transportation Indicator may be:

**Internal interfaces among SCADA, communication systems, pressure-control systems, cathodic protection, monitoring, and operational response are identified and understood.**

Related Quality Outcome Criteria may include:

- internal subsystem interfaces affecting containment, pressure control, corrosion protection, monitoring, or emergency response are identified;
- communication and control dependencies are visible;
- failure or degradation of one subsystem is considered in relation to the behavior of connected subsystems;
- interface assumptions are documented and traceable across lifecycle stages;

- monitoring or control limitations are not treated as evidence of satisfactory performance;
- unresolved interface conditions are reflected in the quality claim boundary.

Quality Outcome Criteria therefore do not merely repeat the Indicator. They define the specific conditions, results, controls, or evidence expectations needed to evaluate whether the Indicator is satisfied.

An Indicator becomes meaningful only when its related Quality Outcome Criteria are clear enough to support a quality determination.

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## 10. Evidence

**Evidence** is information used to support a quality claim about whether relevant Quality Outcome Criteria are met, not met, uncertain, or insufficiently evidenced.

Whole-Quality analysis does not treat evidence as paperwork for its own sake. Evidence must be connected to the quality object, boundary, Quality Factor, Indicator, and Outcome Criteria.

Evidence may include:

- records;
- observations;
- assessments;
- inspection results;
- monitoring data;
- professional evaluations;
- service documentation;
- user or stakeholder feedback;
- test results;
- design assumptions;
- interface records;
- handoff records;
- audit findings;
- corrective-action records;
- or other appropriate sources.

The key principle is:

**Evidence must be sufficient to determine whether the relevant Quality Outcome Criteria are met, not met, uncertain, or insufficiently evidenced.**

Evidence does not replace quality. Documentation does not replace quality. Compliance does not replace quality.

Evidence supports the interpretation of whether the quality object, within the declared boundary and conditions, satisfies the relevant Outcome Criteria.

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## 11. Reference Layer

In many fields, WQI cannot and should not create all detailed evaluation rules internally.

At the Indicator and Quality Outcome Criteria level, the analysis often requires connection to an external **Reference Layer**.

The Reference Layer may include:

- technical standards;
- professional guidelines;
- clinical guidance;
- diagnostic classifications;
- regulatory requirements;
- assessment tools;
- industry standards;
- occupational classifications;
- engineering codes;
- safety rules;
- evidence-based practices.

WQI does not replace these references. It organizes where they are needed.

This is especially important in complex fields such as human health. WQI should not attempt to reproduce medical, psychiatric, disability, pharmacy, rehabilitation, or clinical knowledge systems. Instead, it identifies where those systems become necessary for responsible evaluation.

The Reference Layer supports the determination of whether Outcome Criteria are met, not met, uncertain, or insufficiently evidenced.

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## 12. Example: Quality Management System

A quality management system is a useful example because the quality object is not a product or service. The object is the **management system itself**.

The general ISO 9000 family, including ISO 9001, provides a familiar reference point for quality management systems. Many industries have then developed sector-specific applications or related standards, such as oil and gas, aviation, automotive, and other fields.

In WQI terms:

**Quality object:** management system

**Boundary:** defined organizational scope of the management system

**Interfaces:** customers, regulators, suppliers, outsourced processes, internal departments, leadership, documented information, operations, and process handoffs

**Intended functions and intended results:** to help the organization consistently meet requirements, control processes, evaluate performance, correct failures, and improve

**Failure-mode families:** unclear scope, weak leadership, uncontrolled processes, unmanaged risk, poor evidence, supplier failures, repeated nonconformities, ineffective corrective action, weak process interaction, lack of improvement

From this, possible Quality Factors may include:

- Purpose and Scope Fitness;
- Customer and Stakeholder Orientation;
- Leadership and Accountability;
- Process Integrity;
- Risk and Opportunity Control;
- Resource and Competence Adequacy;
- Operational Control and Consistency;
- Performance Evaluation;
- Nonconformity and Corrective-Action Capability;
- Improvement and Adaptation;
- External-Relationship Control;
- Documented Information and Traceability.

This example shows that WQI does not need to replace ISO-based systems. Instead, it can analyze the quality structure of the management system as an object and show how Core and Context approaches may be developed.

A WQI Quality Management Systems platform could define a Core structure for management-system quality and then develop context guides or applications for different industries and activities.

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## 13. Example: Human Health as a Whole Object

Human health is an even more complex example.

Here the quality object is not one organ, one disease, one diagnosis, or one age group. The quality object, at the Core level, would be the **human being as a whole living body-mind-person system**.

This includes:

- body systems;
- mental and cognitive functioning;
- mobility;
- sensory function;
- nutrition and metabolism;
- adaptation and resilience;
- daily function;
- environment;
- social participation;
- autonomy and dignity;
- continuity of care and response to change.

A human-health Core would need to define invariant Quality Factors for the whole person before developing context guides for specific areas such as cardiovascular health, neurological health, musculoskeletal health, mental health, elderly health, disability, chronic disease, rehabilitation, and other domains.

This article does not create a health standard, diagnostic tool, treatment guide, or disability evaluation method.

The human-health example is used only to show how the Whole-Quality method can be applied to a complex living system.

At the Indicator and Quality Outcome Criteria level, any serious human-health application would require a strong Reference Layer, including medical, clinical, geriatric, psychiatric, disability, rehabilitation, pharmacy, care-assessment, and regulatory references.

WQI's role would not be to replace those references, but to organize how they support quality evaluation.

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## 14. Existing Applied Examples: AMSI and IQI

The Whole-Quality method is already reflected in two applied initiatives.

### **AMSI — Human Support Services Quality**

The American Support Standards Initiative applies this logic to human support services.

In AMSI, the quality object is not merely a provider organization, funding program, service label, or compliance requirement. The quality object is the support service as actually experienced by the person.

This allows AMSI to examine quality in relation to dignity, safety, participation, stability, communication, functional support, accountability, continuity, and other service-quality dimensions.

### **IQI — Infrastructure Systems Quality**

The Infrastructure Quality Initiative applies the same logic to infrastructure systems.

In IQI, the quality object is not merely a component, document, contractor activity, or regulatory requirement. The quality object is the infrastructure asset or system-of-systems throughout its lifecycle.

This allows IQI to examine infrastructure quality through function realization, boundaries, interfaces, uncertainty, technical assumptions, lifecycle gates, environmental conditions, risk, stakeholder and community effects, evidence interpretation, and bounded quality claims.

AMSI and IQI show that the Whole-Quality method can be used for different objects and contexts while preserving the same disciplined logic.

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## 15. Conclusion

Whole Quality does not begin with indicators.

It begins with the quality object.

Only after the object is defined can its boundaries, interfaces, intended functions, intended results, and failure-mode families be identified.

From that structure, Quality Factors can be derived.

From Quality Factors, multiple Indicators can be developed.

From each Indicator, multiple Quality Outcome Criteria may be established.

Evidence is then used to support a quality claim about whether those Outcome Criteria are met, not met, uncertain, or insufficiently evidenced.

At the appropriate level, external standards and professional references are connected through the Reference Layer.

The central principle is:

**Indicators are not chosen first. They are derived from Quality Factors. Quality Factors are derived from the quality object, its boundaries, interfaces, intended functions, intended results, and failure-mode families.**

This is the foundation of the Whole-Quality method.

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