



QUALITY AND HARM

From Quality Conditions to Harm, Risk, and Safety

Foundational Article 15 — First Edition

Whole-Quality Institute

Table of Contents

Foreword	4
1 Scope	4
2 From Quality Condition to Possible Harm	5
2.1 The Resulting Quality Condition	5
2.2 When a Quality Condition Becomes Harm-Capable.....	5
2.3 Quality Deficiency Without a Demonstrated Harm Pathway.....	6
2.4 Uncertainty About Possible Harm	6
3 Harm-Capable Conditions	7
3.1 Meaning of a Harm-Capable Condition	7
3.2 What Makes a Condition Harm-Capable	7
3.3 Harm-Capable Condition Is Not Harm	8
3.4 Harm-Capable Condition Is Not a Prediction of Harm	8
4 Harm Pathways	9
4.1 Meaning of a Harm Pathway	9
4.2 From Harm-Capable Condition to Possible Harm	9
4.3 Direct and Intermediate Connections	9
4.4 Who or What Could Be Affected	10
4.5 Possible Injury, Damage, or Loss	10
4.6 Evidence Supporting a Harm Pathway	11
5 From Possible Harm to Realized Harm	11
5.1 Conditions of Materialization.....	11
5.2 Why an Existing Harm Pathway May Not Materialize.....	12
5.3 Realized Harm	12
5.4 Traceability From Realized Harm Back to the Quality Condition	13
6 Risk in the Quality–Harm Relationship.....	14
6.1 Risk and Possible Harm	14
6.2 Probability and Severity	14
6.3 Risk Does Not Replace Quality Determination	15
6.4 Quality Deficiency, Harm Potential, and Risk	15
6.5 Uncertainty in Risk Determination	16
7 Safety in the Quality–Harm Relationship.....	16
7.1 Safety and Harm	16
7.2 Safety and Risk.....	17
7.3 Safety Does Not Mean Absence of Quality Deficiency.....	17
7.4 Quality Determination and Safety Determination.....	18
7.5 Why the Determinations Must Remain Distinct	18
8 The Complete Quality–Harm Pathway	19
8.1 From Quality Requirement to Resulting Quality Condition	19

8.2 From Resulting Quality Condition to Harm Pathway	19
8.3 From Harm Pathway to Risk	19
8.4 From Harm Pathway to Realized Harm	20
8.5 Relationship to Safety	20
8.6 What the Complete Sequence Does and Does Not Establish	20
9 The Reference Layer	21
9.1 Why Harm, Risk, and Safety Require an Applicable Basis	21
9.2 Laws, Regulations, Standards, Science, and Other Authoritative Sources	21
9.3 Context-Specific Definitions and Thresholds	22
9.4 Conflicting or Incomplete References	22
9.5 Traceability to the Applicable Basis	23
10 Boundaries Between Quality, Harm, Risk, and Safety	23
10.1 Quality Is Not Harm	23
10.2 Harm Potential Is Not Realized Harm	24
10.3 Risk Is Not Harm	24
10.4 Safety Is Not Quality	24
10.5 One Determination Cannot Automatically Substitute for Another	25
11 Limits and Further Research	25
12 Conclusion	26
Copyright and Use Notice	27

Foreword

Quality and Harm are related, but they are not the same.

Foundational Article 14 introduced the Dual-Nature Postulate:

Every invariant Quality Factor and Quality Indicator possesses both a Quality nature and a latent Harm-related nature.

It also established an important boundary. A Quality deficiency does not automatically mean that Harm exists or will occur.

This Article examines what happens between a resulting Quality condition and possible Harm.

Where a resulting Quality condition is a Quality deficiency, it may remain only a Quality deficiency. In another case, it may be Harm-capable because a credible connection to possible injury, damage, or loss can be demonstrated.

Even then, Harm does not necessarily occur. The pathway must proceed under the circumstances necessary for Harm to become realized.

This creates a sequence:

resulting Quality condition

→ **Harm-capable condition, where demonstrated**

→ **Harm pathway, where demonstrated**

→ **possible injury, damage, or loss**

→ **conditions of materialization**

→ **realized Harm, where those conditions occur.**

Risk and Safety are related to this sequence, but they are not substitutes for Quality or Harm.

Risk concerns possible Harm and its probability and severity. Safety concerns the acceptability or tolerability of Risk within the Applicable Basis. Their particular meaning, criteria, and thresholds may depend on the field, jurisdiction, and purpose of the determination.

This Article therefore examines how Quality, Harm, Risk, and Safety relate while remaining distinct.

The purpose is not to turn Quality Determination into Risk or Safety determination. It is to show, step by step, when a Quality condition has a demonstrated connection to possible Harm and how Risk and Safety can then be considered while the original Quality condition remains traceable.

1 Scope

This Foundational Article examines the relationship between resulting Quality conditions, Harm, Risk, and Safety.

It begins where Foundational Article 14 leaves the Quality–Harm sequence: with a resulting Quality condition.

The Article examines how such a condition may remain only a Quality deficiency or, where a credible connection to possible injury, damage, or loss can be demonstrated, may be identified as a Harm-capable condition.

It then examines how a Harm-capable condition can support a Harm pathway, how that pathway can lead to possible Harm, and what conditions are necessary for Harm to become realized.

The Article also examines where Risk and Safety enter this relationship.

Quality, Harm, Risk, and Safety remain distinct. A finding concerning one does not automatically establish a finding concerning another.

The Article therefore addresses:

- resulting Quality conditions and Harm-capable conditions;
- Harm pathways and possible Harm;
- conditions of materialization and realized Harm;
- the relationship between Harm and Risk;
- the relationship between Risk and Safety;
- the role of the Reference Layer; and
- the boundaries among Quality, Harm, Risk, and Safety.

The Article does not establish universal Risk or Safety thresholds, technical acceptance limits, or requirements for any particular service, infrastructure system, industry, or jurisdiction. It also does not provide detailed testing of the framework across WQI applications or establish the full methodology for Evidence Quality and Quality Determination. Those subjects are reserved for later articles in the Quality and Harm set.

Its purpose is to explain how a resulting Quality condition can be examined for a possible connection to Harm and, where applicable, related to Risk and Safety without treating these different determinations as interchangeable. The Article establishes these relationships; it does not claim that they have been universally demonstrated.

2 From Quality Condition to Possible Harm

2.1 The Resulting Quality Condition

The Quality–Harm analysis begins with a resulting Quality condition.

A resulting Quality condition is the condition identified through Quality Determination. If the required Quality outcome is not achieved, that condition is a Quality deficiency.

For example, required assistance may be unavailable, required information may be inaccurate, or a physical system may not maintain a required condition.

At this point, the finding concerns Quality.

The resulting Quality condition does not by itself establish:

- a Harm-capable condition;
- a Harm pathway;
- possible Harm;
- Risk; or
- realized Harm.

The next question is whether the identified Quality condition has a credible connection to possible injury, damage, or loss.

This connection should be demonstrated rather than assumed.

If no credible connection is demonstrated, the condition remains a Quality deficiency without a demonstrated Harm pathway.

If a credible connection is demonstrated, the resulting Quality condition may be identified as Harm-capable.

If the available Evidence does not support either conclusion, the possible relationship to Harm remains uncertain.

The resulting Quality condition therefore provides the starting point for examining possible Harm while preserving the distinction between a Quality deficiency and Harm.

2.2 When a Quality Condition Becomes Harm-Capable

A resulting Quality condition becomes Harm-capable when a credible connection can be demonstrated between that condition and possible injury, damage, or loss.

The condition does not need to have already caused Harm.

It must, however, be capable of supporting a credible pathway through which Harm could occur.

For this Article:

Harm-capable condition — A resulting Quality condition capable, under identifiable circumstances, of supporting a credible pathway through which injury, damage, or loss can become realized.

A Quality deficiency alone does not establish a Harm-capable condition.

There must be a credible connection between the identified condition and possible Harm.

For example, the analysis should be able to identify:

- the resulting Quality condition;
- who or what could be affected; and
- the possible injury, damage, or loss.

At this stage, it is not necessary to establish that Harm will occur.

The question is whether the resulting Quality condition can support a credible path toward Harm.

Where that connection is demonstrated, the condition can be identified as Harm-capable.

Where it is not demonstrated, the finding remains a Quality deficiency without a demonstrated Harm pathway.

2.3 Quality Deficiency Without a Demonstrated Harm Pathway

A Quality deficiency can exist without a demonstrated Harm pathway.

A required Quality outcome may not be achieved, but the resulting condition may have no demonstrated connection to possible injury, damage, or loss.

In that case, the finding should remain a Quality finding.

The absence of a demonstrated Harm pathway does not make the Quality deficiency less important. It means only that a credible path from that condition to possible Harm has not been established.

The distinction is:

Quality deficiency

≠

automatically a Harm-capable condition.

A Harm pathway should not be assumed simply because a Quality requirement was not achieved.

It should also not be created merely to give the Quality deficiency a Harm-related explanation.

The analysis should remain bounded by what can be supported.

If a credible Harm pathway is not demonstrated, the appropriate finding is:

Quality deficiency without a demonstrated Harm pathway.

This preserves the Quality finding without making a Harm conclusion that the available Evidence does not support.

2.4 Uncertainty About Possible Harm

Sometimes the available Evidence does not establish whether a resulting Quality condition has a credible path to possible Harm.

In that case, the relationship should remain uncertain.

Uncertainty is different from finding that no Harm pathway exists.

The distinction is:

No demonstrated Harm pathway

→ **the available Evidence does not demonstrate a credible pathway.**

Uncertain Harm pathway

→ **the available Evidence does not support a sufficient conclusion about whether a credible pathway exists.**

This distinction matters.

Lack of sufficient Evidence should not be treated as proof that a Quality condition cannot lead to Harm.

At the same time, uncertainty should not be treated as proof that a Harm pathway exists.

The finding should therefore state clearly what is known, what is not known, and what remains uncertain.

This allows the Quality deficiency to remain established while the possible path to Harm remains unresolved.

3 Harm-Capable Conditions

3.1 Meaning of a Harm-Capable Condition

A Harm-capable condition is a resulting Quality condition for which a credible connection to possible injury, damage, or loss can be demonstrated and that is capable of supporting a credible pathway to that Harm.

The condition is already present.

The Harm may not be.

Harm-capable condition — A resulting Quality condition capable, under identifiable circumstances, of supporting a credible pathway through which injury, damage, or loss can become realized.

Three elements are important.

First, there must be an identified resulting Quality condition.

Second, there must be a credible connection between that condition and possible injury, damage, or loss.

Third, the circumstances under which that connection can operate must be identifiable.

A Harm-capable condition therefore goes beyond identifying a Quality deficiency: it identifies a condition capable of supporting a credible pathway to possible Harm.

It does not establish the pathway itself.

Nor does it establish that Harm has occurred or will occur.

This distinction allows a condition to be recognized as Harm-capable before injury, damage, or loss becomes realized.

3.2 What Makes a Condition Harm-Capable

A resulting Quality condition is Harm-capable when the required connection to possible injury, damage, or loss can be demonstrated.

That connection must be grounded in the actual condition.

The connection should identify:

- the resulting Quality condition;
 - the person, property, environment, or other subject or interest that could be affected;
 - the possible injury, damage, or loss; and
 - a credible way through which the condition could lead to that Harm.
- The connection may be direct or may involve intermediate conditions, actions, failures, or changes.

The possibility of Harm alone is not enough.

There must be a credible connection between the identified Quality condition and the possible Harm.

Evidence should support that connection.

Where the connection is demonstrated, the resulting Quality condition can be identified as Harm-capable.

Where the connection is not demonstrated, the condition remains a Quality deficiency without a demonstrated Harm pathway.

Where the available Evidence is insufficient to determine the connection, the possible relationship to Harm remains uncertain.

This keeps the finding tied to the actual Quality condition and to what the Evidence supports.

3.3 Harm-Capable Condition Is Not Harm

A Harm-capable condition is not the same as Harm.

It means that a resulting Quality condition is capable of supporting a credible pathway to injury, damage, or loss.

Harm is realized only when injury, damage, or loss actually occurs.

The distinction is:

Harm-capable condition

→ **the condition is capable of supporting a credible pathway to possible Harm.**

Realized Harm

→ **injury, damage, or loss has occurred.**

A Harm-capable condition may exist without realized Harm.

If a Harm pathway is separately established, it may be interrupted, protective measures may prevent Harm, or the circumstances necessary for Harm to occur may never arise.

The existence of a Harm-capable condition therefore establishes neither that a Harm pathway has been fully demonstrated nor that Harm has occurred or will occur.

It establishes that the resulting Quality condition is capable of supporting a credible pathway to possible Harm. The pathway itself must be established separately and remain traceable to that condition.

3.4 Harm-Capable Condition Is Not a Prediction of Harm

Identifying a condition as Harm-capable does not predict that Harm will occur.

The identification establishes that the condition is capable of supporting a credible pathway to possible injury, damage, or loss.

If a Harm pathway is established, whether Harm becomes realized depends on the conditions of materialization.

Those conditions may arise, may be prevented, or may never occur.

A Harm-capable condition therefore supports a statement about capability, not about future outcome.

It should not be interpreted as establishing:

- that Harm will occur;
- when Harm will occur;
- how likely Harm is to occur; or
- how severe the Harm will be.

Questions about likelihood and severity belong to Risk determination where those concepts are applicable.

Identifying a Harm-capable condition, establishing a Harm pathway, and determining Risk are therefore separate steps.

A condition can therefore be identified as Harm-capable without predicting whether its possible Harm will become realized.

4 Harm Pathways

4.1 Meaning of a Harm Pathway

A Harm pathway is the connection through which a Harm-capable condition can lead to injury, damage, or loss.

For this Article:

Harm pathway — An evidence-supported sequence or connection through which a Harm-capable condition can lead to injury, damage, or loss affecting an identifiable subject or interest.

A Harm pathway therefore connects:

- the Harm-capable condition;
- the person, property, environment, or other subject or interest that could be affected; and
- the possible injury, damage, or loss.

The pathway may be direct or may include intermediate conditions, actions, failures, or changes.

The pathway must be supported by Evidence.

It should not be assumed merely because a Harm-capable condition has been identified.

Establishing the pathway also does not mean that Harm has occurred or will occur.

It establishes a traceable connection through which the identified condition can lead to possible Harm.

Whether that Harm becomes realized depends on the circumstances necessary for the pathway to proceed.

4.2 From Harm-Capable Condition to Possible Harm

A Harm-capable condition identifies the capability to support a credible path toward possible Harm.

A separately established Harm pathway identifies that path.

The sequence is:

Harm-capable condition

→ **Harm pathway**

→ **possible injury, damage, or loss.**

Each part should remain traceable to the one before it.

The possible Harm should arise from the identified pathway rather than from a general assumption that the Quality deficiency could be harmful.

The analysis should therefore identify:

- the Harm-capable condition;
- the pathway through which the condition can lead to Harm;
- who or what could be affected; and
- the possible injury, damage, or loss.

At this stage, the Harm remains possible.

The existence of the pathway does not establish that the circumstances necessary for Harm to become realized will occur.

Once established, the pathway shows how the identified condition can lead to possible Harm.

Whether that Harm becomes realized is a separate question addressed in Section 5.

4.3 Direct and Intermediate Connections

A Harm pathway may connect a Harm-capable condition to possible Harm directly or through one or more intermediate steps.

A direct connection exists when the condition can lead to injury, damage, or loss without another significant step in the pathway.

An intermediate connection exists when the pathway proceeds through additional conditions, actions, failures, or changes before Harm can occur.

The pathway may therefore take either form:

Harm-capable condition

→ **possible Harm**

or:

Harm-capable condition

→ **intermediate step or steps**

→ **possible Harm.**

Intermediate steps should be identified when they are necessary to explain how the possible Harm can arise.

They should not be added merely to make a pathway appear more complete.

Each necessary connection should be supported by Evidence and remain traceable to the Harm-capable condition.

Whether the pathway is direct or intermediate does not determine whether Harm will become realized.

It describes how the identified condition can lead to possible Harm.

4.4 Who or What Could Be Affected

A Harm pathway must identify who or what could be affected.

For this Article, the affected subject or interest may include:

- a person or group of people;
- property;
- the environment; or
- another defined subject or interest.

The analysis should identify clearly who or what could experience the possible injury, damage, or loss.

The same Harm-capable condition may affect more than one person, property, environmental feature, or other defined interest.

They may also be affected through different Harm pathways.

Who or what could be affected should therefore be identified for each pathway rather than assumed from the Quality deficiency alone.

This creates a traceable connection:

Harm-capable condition

→ **Harm pathway**

→ **affected subject or interest**

→ **possible injury, damage, or loss.**

Identifying who or what could be affected does not establish that Harm has occurred.

It identifies who or what could experience the possible Harm if the pathway proceeds.

4.5 Possible Injury, Damage, or Loss

A Harm pathway should identify the possible Harm to which it can lead.

For this Article, Harm means injury, damage, or loss affecting a person, property, environment, or another defined subject or interest.

The possible Harm should be stated clearly enough to show what could happen and what could be affected.

It should not be described more broadly than the pathway and available Evidence support.

A single Harm-capable condition may support:

- one possible form of Harm;
- several different forms of Harm; or
- Harm affecting more than one subject or interest.

Each identified form of possible Harm should remain traceable through the pathway to the Harm-capable condition.

At this stage, possible Harm is not realized Harm.

It identifies the injury, damage, or loss that can result if the pathway proceeds under the circumstances necessary for Harm to occur.

This distinction allows possible Harm to be identified without claiming that it has occurred or will occur.

4.6 Evidence Supporting a Harm Pathway

A Harm pathway must be supported by Evidence.

The Evidence should support the connections between:

- the Harm-capable condition;
- any necessary intermediate steps;
- the affected subject or interest; and
- the possible injury, damage, or loss.

Evidence may come from different sources depending on the Quality Object, context, and pathway being examined.

The required Evidence should therefore be determined in relation to the Applicable Basis and the particular pathway.

A pathway should not be treated as established merely because it is imaginable or theoretically possible.

The Evidence should be sufficient to support a credible connection from the identified condition to the possible Harm.

Where the Evidence supports that connection, the Harm pathway can be established.

Where it does not, a Harm pathway should not be claimed.

Where the Evidence is insufficient to reach either conclusion, the pathway remains uncertain.

This keeps the Harm pathway traceable to both the resulting Quality condition and the Evidence that supports the connection to possible Harm.

5 From Possible Harm to Realized Harm

5.1 Conditions of Materialization

A Harm pathway can exist without Harm becoming realized.

For possible Harm to become realized, the circumstances necessary for the pathway to proceed must occur.

For this Article:

Conditions of materialization — The circumstances necessary for an existing Harm pathway to proceed to realized Harm.

These conditions are different from the conditions that make a Quality condition Harm-capable or establish the Harm pathway itself.

They do not create the latent Harm potential.

They also do not create the Harm pathway.

Instead, they determine whether an existing pathway proceeds to actual injury, damage, or loss.

Conditions of materialization may involve:

- exposure of the affected subject or interest;
- continuation or worsening of an existing condition;
- occurrence of an additional event or change;
- failure or absence of a protective measure; or
- another circumstance necessary for the pathway to proceed.

The particular conditions depend on the Harm pathway and its context.

If the necessary conditions occur, the pathway may proceed to realized Harm.

If they do not occur, the Harm pathway may continue to exist without Harm becoming realized.

This distinction separates the existence of a Harm pathway from its materialization into actual injury, damage, or loss.

5.2 Why an Existing Harm Pathway May Not Materialize

An existing Harm pathway does not necessarily proceed to realized Harm.

The pathway may remain incomplete because one or more conditions necessary for materialization do not occur.

For example:

- the affected subject or interest may not be exposed;
- the condition may be corrected before Harm occurs;
- a protective measure may interrupt the pathway;
- an intermediate event necessary for the pathway may not occur; or
- the circumstances necessary for Harm may otherwise remain absent.

These circumstances do not mean that the Harm pathway never existed.

They mean that the existing pathway did not proceed to realized Harm.

Absence of realized Harm therefore does not establish absence of a Harm-capable condition or Harm pathway.

The analysis should therefore preserve the difference between:

Harm pathway exists

→ **Harm is possible;**

and

Harm pathway materializes

→ **injury, damage, or loss occurs.**

A pathway that does not materialize remains an established pathway even though no realized Harm results.

5.3 Realized Harm

Realized Harm exists when injury, damage, or loss has actually occurred.

It is therefore different from possible Harm.

The sequence is:

Harm-capable condition

→ **Harm pathway**

→ **possible Harm**

→ **conditions of materialization**

→ **realized Harm.**

For this Article, realized Harm requires an identifiable injury, damage, or loss affecting a person, property, environment, or another defined subject or interest.

The occurrence of Harm should be supported by Evidence.

The analysis should identify:

- what injury, damage, or loss occurred;
- who or what was affected;
- the Harm pathway through which it occurred; and
- the resulting Quality condition from which that pathway arose.

Realized Harm does not replace the underlying Quality finding.

The Quality condition and the realized Harm are different findings connected through the Harm pathway.

Keeping them distinct allows the analysis to show both what was deficient in Quality and what injury, damage, or loss actually resulted.

This preserves traceability from realized Harm back through the Harm pathway to the resulting Quality condition.

5.4 Traceability From Realized Harm Back to the Quality Condition

When Harm becomes realized, the connection to the original resulting Quality condition should remain traceable.

The traceable sequence is:

resulting Quality condition

→ **Harm-capable condition**

→ **Harm pathway**

→ **possible Harm**

→ **conditions of materialization**

→ **realized Harm.**

Traceability should also work in the opposite direction:

realized Harm

→ **Harm pathway**

→ **Harm-capable condition**

→ **resulting Quality condition.**

This allows the analysis to identify how the realized injury, damage, or loss is connected to the original Quality finding.

The connection should be supported by Evidence at each necessary step.

Realized Harm should not be attributed to a Quality condition merely because both exist.

The Evidence should support the pathway connecting them.

Where that connection is supported, the analysis can trace the realized Harm back to the resulting Quality condition.

Where the connection is not supported, the existence of Harm and the existence of a Quality deficiency should remain separate findings.

This preserves the distinction between identifying Harm and establishing how that Harm is connected to Quality.

6 Risk in the Quality–Harm Relationship

6.1 Risk and Possible Harm

Risk provides a way to evaluate possible Harm.

A Harm pathway identifies how a Harm-capable condition can lead to injury, damage, or loss. Risk then considers two principal dimensions:

- the probability that the Harm will occur; and
- the severity of the Harm if it occurs.

For this Article, Risk is considered through probability and severity.

This adds a separate Risk determination to the Quality–Harm sequence.

The sequence is:

resulting Quality condition

→ **Harm-capable condition**

→ **Harm pathway**

→ **possible Harm**

→ **probability and severity**

→ **Risk.**

The Harm pathway answers:

How can Harm occur?

Risk addresses different questions:

How likely is that Harm to occur?

How severe could that Harm be?

The methods, scales, categories, calculations, and thresholds used to determine Risk may differ among fields, jurisdictions, and purposes.

They should therefore come from the Applicable Basis rather than from a universal WQI measurement system.

Risk is related to possible Harm, but it remains a distinct determination.

6.2 Probability and Severity

Risk determination considers probability and severity together for purposes of this Article.

Probability concerns how likely it is that the identified Harm will occur through the Harm pathway.

Severity concerns how serious the injury, damage, or loss would be if that Harm occurs.

These are different dimensions.

A Harm pathway may have:

- a higher probability of less severe Harm;
- a lower probability of more severe Harm; or
- other combinations of probability and severity.

Neither dimension should therefore be considered alone when the Applicable Basis requires both.

The determination should begin with the specific Harm already identified through the Harm pathway.

It should then determine:

- the probability of that Harm occurring; and
- the severity of that Harm if it occurs.

The methods used may be quantitative, qualitative, or a combination of both.

The Applicable Basis should establish the appropriate method, categories, scales, assumptions, and thresholds for the particular context.

WQI does not assign a universal numerical value or category to probability or severity.

It establishes their place in the sequence:

possible Harm

→ **probability and severity**

→ **Risk determination.**

This keeps Risk connected to the specific Harm pathway while keeping Risk determination distinct from the underlying Quality determination.

6.3 Risk Does Not Replace Quality Determination

Risk determination and Quality Determination answer different questions.

Quality Determination examines whether the required Quality outcome has been achieved.

Risk determination evaluates possible Harm through probability and severity.

A Risk determination therefore does not replace the underlying Quality Determination.

For example, a Quality deficiency does not become acceptable merely because the associated Risk is determined to be low.

Likewise, a higher Risk does not make the original Quality deficiency greater or smaller.

The determinations remain distinct:

Quality Determination

→ **What Quality condition exists?**

Harm analysis

→ **Can that condition lead to injury, damage, or loss, and through what pathway?**

Risk determination

→ **How probable is that Harm, and how severe would it be?**

Each determination provides different information.

They may be used together, but the result of one should not be substituted for the result of another.

This preserves the original Quality finding while allowing the associated Risk to be determined separately.

6.4 Quality Deficiency, Harm Potential, and Risk

Quality deficiency, Harm potential, and Risk describe different parts of the Quality–Harm relationship.

A Quality deficiency exists when a required Quality outcome is not achieved.

Latent Harm potential exists at the level of the invariant Quality Factor or Quality Indicator within its applicable Core.

A particular Quality deficiency may express that Harm potential as a Harm-capable condition and, where separately demonstrated, through a Harm pathway.

Risk can then be determined in relation to the possible Harm identified through that pathway.

The sequence is:

Quality deficiency

→ **Harm-capable condition, where demonstrated**

→ **Harm pathway, where demonstrated**

→ **possible Harm**

→ **probability and severity**

→ **Risk.**

These distinctions should be preserved.

The existence of a Quality deficiency does not by itself establish Risk.

The existence of latent Harm potential does not establish that a particular Harm pathway exists.

A Harm pathway does not by itself establish the probability or severity of the possible Harm.

Risk determination therefore requires its own Evidence and Applicable Basis.

This keeps Risk traceable to the possible Harm and Harm pathway without treating Risk as a measure of the Quality deficiency itself.

6.5 Uncertainty in Risk Determination

A Risk determination may remain uncertain.

The Harm pathway may be established, while the available Evidence does not support a sufficiently certain determination of probability, severity, or both.

Uncertainty may arise from:

- limited or incomplete Evidence;
- variability in the conditions affecting the Harm pathway;
- uncertainty about exposure or other conditions of materialization;
- limited knowledge about the possible consequences; or
- limitations in the method used to determine Risk.

Uncertainty should not be hidden by assigning a Risk value or category that the Evidence cannot support.

The determination should distinguish between:

- what is supported by the Evidence;
- what remains uncertain; and
- what cannot presently be determined.

Uncertainty about Risk does not remove the underlying Quality deficiency, Harm-capable condition, or Harm pathway where those findings have already been established.

It means that the probability, severity, or resulting Risk cannot be determined with the same level of certainty.

The treatment of uncertainty should follow the Applicable Basis for the particular Risk determination.

This preserves the boundaries among established Quality findings, established Harm pathways, and uncertainty in the determination of Risk.

7 Safety in the Quality–Harm Relationship

7.1 Safety and Harm

Safety concerns Harm, but Safety and Harm are not the same.

Harm describes injury, damage, or loss.

Safety concerns whether the Risk associated with possible Harm is acceptable or tolerable according to the Applicable Basis.

Safety therefore enters the sequence after possible Harm and its Risk have been considered.

The relationship can be expressed as:

possible Harm

→ **probability and severity**

→ **Risk**

→ **evaluation of Risk against applicable criteria**

→ **Safety determination.**

The absence of realized Harm does not by itself establish Safety.

A Harm pathway may exist even when no injury, damage, or loss has yet occurred.

Likewise, the existence of possible Harm does not by itself establish that a condition is unsafe.

The associated Risk must be evaluated according to the applicable Safety criteria.

Those criteria may differ among fields, jurisdictions, Quality Objects, and purposes.

WQI therefore does not establish a universal threshold separating safe from unsafe conditions.

The Safety determination should follow the Applicable Basis and remain traceable to the Risk, possible Harm, Harm pathway, and underlying Quality condition.

7.2 Safety and Risk

Safety and Risk are closely related, but they are not the same determination.

Risk is determined by considering the probability and severity of possible Harm.

Safety considers that Risk against the criteria established by the Applicable Basis.

The relationship is:

possible Harm

→ **probability and severity**

→ **Risk**

→ **applicable Safety criteria**

→ **Safety determination.**

A Risk value, level, or category does not by itself establish whether something is safe or unsafe.

The Risk must be compared with the applicable criteria for its particular context.

The evaluation of a Risk may differ where different Applicable Bases, purposes, or conditions apply.

Safety determination therefore requires both:

- a Risk determination; and
- applicable criteria for evaluating that Risk.

WQI does not establish a universal Risk level at which Safety begins or ends.

That boundary must come from the Applicable Basis.

This keeps Safety connected to Risk while preserving Safety as a separate determination.

7.3 Safety Does Not Mean Absence of Quality Deficiency

A Safety determination does not determine whether a Quality deficiency exists.

A Quality deficiency exists when a required Quality outcome is not achieved.

Safety is determined separately by evaluating Risk against the applicable Safety criteria.

A condition may therefore have a Quality deficiency even when the associated Risk is considered acceptable or tolerable under the Applicable Basis.

The distinction is:

Quality Determination

→ **Was the required Quality outcome achieved?**

Safety determination

→ **Is the associated Risk acceptable or tolerable under the applicable Safety criteria?**

A finding of Safety does not erase, correct, or change the underlying Quality deficiency.

Likewise, the absence of a Quality deficiency does not by itself establish Safety. Safety may depend on Harm pathways and Risks that must be examined according to the Applicable Basis.

Quality and Safety should therefore remain separate findings.

This allows the Quality condition to be reported as it exists while Safety is determined according to the applicable Risk and Safety criteria.

7.4 Quality Determination and Safety Determination

Quality Determination and Safety determination have different purposes.

Quality Determination establishes the Quality condition by examining whether the required Quality outcome has been achieved.

Safety determination evaluates whether the Risk associated with possible Harm is acceptable or tolerable according to the Applicable Basis.

The same Quality Object may therefore be examined by both determinations, but each answers a different question.

Quality Determination asks:

What Quality condition exists in relation to the applicable Quality requirement?

Safety determination asks:

Is the Risk associated with the identified possible Harm acceptable or tolerable under the applicable Safety criteria?

The Evidence, methods, and criteria needed for the two determinations may also differ.

Their results should therefore remain separately identifiable and traceable.

Where a Quality deficiency contributes to a Harm pathway, the Safety determination can remain connected to that deficiency through the sequence:

Quality deficiency

- **Harm-capable condition**
- **Harm pathway**
- **possible Harm**
- **probability and severity**
- **Risk**
- **applicable Safety criteria**
- **Safety determination.**

This connection allows Quality and Safety to be examined together without treating them as the same determination.

7.5 Why the Determinations Must Remain Distinct

Quality Determination and Safety determination may be connected, but one should not substitute for the other.

A Quality Determination establishes whether the required Quality outcome has been achieved.

A Safety determination establishes whether the Risk associated with possible Harm is acceptable or tolerable according to the Applicable Basis.

If these determinations are combined into a single finding, important information can be lost.

For example:

- an acceptable or tolerable Risk could hide an existing Quality deficiency;
 - a Quality deficiency could be treated as automatically unsafe without a Risk and Safety determination;
or
 - the connection between the Quality condition, possible Harm, Risk, and Safety could become unclear.
- Keeping the determinations distinct preserves the full sequence:

Quality condition

- **Harm-capable condition, where demonstrated**
- **Harm pathway, where demonstrated**

- **possible Harm**
- **probability and severity**
- **Risk**
- **applicable Safety criteria**
- **Safety determination.**

Each finding can then be supported by its own Evidence and Applicable Basis while remaining traceable to the other findings.

The determinations can therefore inform one another without becoming interchangeable.

This preserves both the Quality finding and the Safety finding and makes their relationship explicit.

8 The Complete Quality–Harm Pathway

8.1 From Quality Requirement to Resulting Quality Condition

The complete Quality–Harm pathway begins with the applicable Quality requirement.

The requirement establishes the Quality outcome that is expected for the Quality Object.

Evidence is then used to determine whether that required outcome has been achieved.

The basic Quality sequence is:

Quality requirement

- **Evidence**
- **Quality Determination**
- **resulting Quality condition.**

Where the required Quality outcome is achieved, the resulting condition reflects that achievement.

Where the required Quality outcome is not achieved, a Quality deficiency exists.

The existence of a Quality deficiency does not by itself establish Harm, Risk, or a Safety finding.

It establishes the Quality condition from which the possible connection to Harm can then be examined.

The next question is whether that resulting Quality condition can support a credible pathway to injury, damage, or loss.

This keeps the Quality Determination as the starting point while allowing the analysis to proceed toward Harm only where the Evidence supports that connection.

8.2 From Resulting Quality Condition to Harm Pathway

Section 8 brings the preceding steps into one sequence. A resulting Quality condition may remain only a Quality finding or may support progression toward Harm.

Where the required connections are demonstrated, the sequence is:

resulting Quality condition

- **Harm-capable condition**
- **Harm pathway**
- **possible Harm.**

Where a Harm pathway is not demonstrated, the Quality deficiency remains without a demonstrated Harm pathway.

Where the Evidence is insufficient, the possible connection to Harm remains uncertain.

These distinctions preserve the Quality finding while establishing only those further connections that the Evidence supports.

8.3 From Harm Pathway to Risk

Once a Harm pathway and possible Harm have been identified, Risk can be determined where applicable.

The sequence is:

Harm pathway

- **possible Harm**
- **probability and severity**
- **Risk.**

The Harm pathway identifies how the Harm can occur.

Risk adds the determination of how probable that Harm is and how severe it would be if it occurs.

The method, scales, and thresholds used for that determination come from the Applicable Basis.

Risk remains a separate determination based on the possible Harm identified through the pathway.

8.4 From Harm Pathway to Realized Harm

A Harm pathway does not mean that Harm will become realized.

The sequence is:

Harm pathway

- **possible Harm**
- **conditions of materialization**
- **realized Harm, where those conditions occur.**

The conditions of materialization determine whether the existing pathway proceeds to actual injury, damage, or loss.

If the necessary conditions do not occur, the pathway may continue to exist without realized Harm.

Realized Harm occurs only where the pathway proceeds under the necessary conditions of materialization.

8.5 Relationship to Safety

Safety adds another determination to the complete sequence.

The relationship is:

possible Harm

- **probability and severity**
- **Risk**
- **applicable Safety criteria**
- **Safety determination.**

Risk describes the probability and severity of the possible Harm.

Safety evaluates that Risk against the criteria established by the Applicable Basis.

The Safety determination therefore remains connected to the Harm pathway and the underlying Quality condition while remaining distinct from both.

This preserves traceability from the original Quality condition through Harm and Risk to Safety.

8.6 What the Complete Sequence Does and Does Not Establish

The complete sequence integrates the separate determinations described above.

The sequence is:

Quality requirement

- **Evidence**
- **Quality Determination**
- **resulting Quality condition**
- **Harm-capable condition, where demonstrated**
- **Harm pathway, where demonstrated**
- **possible Harm**

- **probability and severity**
- **Risk, where determined**
- **applicable Safety criteria**
- **Safety determination.**

A separate branch shows whether possible Harm becomes realized:

Harm pathway

- **possible Harm**
- **conditions of materialization**
- **realized Harm, where those conditions occur.**

The sequence establishes the relationships among these findings and determinations.

It does not establish that every Quality deficiency is Harm-capable, that every Harm-capable condition leads to realized Harm, or that every identified Harm pathway has the same Risk.

It also does not establish universal Risk or Safety thresholds.

Each step should be supported by the Evidence and Applicable Basis required for that determination.

The complete sequence therefore provides traceability without treating Quality, Harm, Risk, and Safety as interchangeable findings.

9 The Reference Layer

9.1 Why Harm, Risk, and Safety Require an Applicable Basis

Harm, Risk, and Safety cannot be determined only from the existence of a Quality deficiency.

Their determination requires an Applicable Basis appropriate to the Quality Object, context, and purpose of the determination.

The Applicable Basis provides the authoritative foundation for deciding, as applicable:

- what constitutes injury, damage, or loss;
- what Evidence supports a Harm pathway;
- how probability and severity are determined;
- how Risk is evaluated; and
- what criteria are used for Safety determination.

The Applicable Basis may differ among fields, jurisdictions, Quality Objects, and purposes.

For this reason, WQI does not create universal definitions, thresholds, or acceptance criteria where these must be established by the applicable field or authority.

The Reference Layer identifies the sources that provide this basis.

This allows Harm, Risk, and Safety determinations to remain connected to the complete Quality–Harm pathway while being grounded in the requirements, knowledge, and criteria applicable to the particular context.

9.2 Laws, Regulations, Standards, Science, and Other Authoritative Sources

The Reference Layer may include different authoritative sources.

Depending on the Quality Object and context, these may include:

- laws and regulations;
- technical and professional standards;
- scientific knowledge and research;
- regulatory or professional guidance; and
- other authoritative sources applicable to the determination.

Different sources may support different parts of the Quality–Harm pathway.

For example, one source may establish a required condition, another may provide evidence about how injury or damage can occur, and another may establish the method or criteria for Risk or Safety determination.

Each source should be used only for the part of the determination that it can support.

Its authority, scope, and applicability should also be considered.

The Reference Layer does not replace the Evidence concerning the actual Quality condition or Harm pathway.

It provides the basis against which that Evidence can be interpreted and the relevant determinations can be made.

This allows each part of the Quality–Harm relationship to remain traceable both to the Evidence and to the authoritative basis supporting the determination.

9.3 Context-Specific Definitions and Thresholds

Definitions, measurement methods, and thresholds for Harm, Risk, and Safety may differ among contexts.

For example, the Applicable Basis may establish:

- what constitutes a particular form of injury, damage, or loss;
- how probability and severity are defined or measured;
- how Risk levels or categories are determined;
- what Risk is considered acceptable or tolerable; and
- what conditions or thresholds apply to a Safety determination.

These definitions and thresholds should not be assumed to apply universally.

They should be identified from the Reference Layer applicable to the particular Quality Object, context, and purpose of the determination.

Where more than one definition, method, or threshold applies, each should remain traceable to its source and scope.

WQI provides the methodological relationship among Quality, Harm, Risk, and Safety.

It does not replace context-specific definitions or thresholds established by the Applicable Basis.

This allows the same Quality–Harm framework to be used across different contexts without imposing requirements that belong to a particular field or jurisdiction.

9.4 Conflicting or Incomplete References

The Reference Layer may not always provide one clear and complete basis for a determination.

Different sources may use different definitions, methods, thresholds, or criteria.

Some sources may also be incomplete for the particular Quality Object, context, or Harm pathway being examined.

A source should not be chosen simply to remove the disagreement or fill the gap.

The determination should identify:

- which sources apply;
- where the sources differ or leave gaps;
- which parts of the determination each source can support; and
- what uncertainty remains because of the conflict or missing information.

Where the Applicable Basis establishes how conflicting sources should be prioritized or reconciled, that basis should be followed.

Where it does not, the conflict or gap should remain explicit.

A determination should not appear more certain or complete than its Reference Layer supports.

This preserves traceability and prevents uncertainty in the Applicable Basis from being hidden within a Harm, Risk, or Safety determination.

9.5 Traceability to the Applicable Basis

Each Harm, Risk, and Safety determination should remain traceable to the Applicable Basis that supports it.

Traceability should identify:

- the relevant source in the Reference Layer;
- the definition, method, criterion, or threshold taken from that source;
- the part of the determination to which it applies; and
- the Evidence used in making the determination.

This creates a traceable connection between:

Applicable Basis

→ **Evidence**

→ **determination**

→ **finding.**

Different parts of the Quality–Harm pathway may rely on different sources.

The source supporting a Harm pathway, for example, may differ from the source establishing a Risk method or a Safety threshold.

These sources should remain separately identifiable rather than being treated as one general authority.

Where the Applicable Basis changes, the effect on the determination should also be identifiable.

Traceability shows both what was determined and the basis for that determination.

This keeps Harm, Risk, and Safety determinations transparent, reviewable, and connected to their supporting sources.

10 Boundaries Between Quality, Harm, Risk, and Safety

10.1 Quality Is Not Harm

Quality and Harm are related, but they describe different findings.

Quality concerns whether the required Quality outcome has been achieved.

Harm concerns injury, damage, or loss affecting a person, property, environment, or another defined subject or interest.

A Quality deficiency may provide the starting condition for a Harm pathway, but the deficiency itself is not Harm.

The distinction is:

Quality deficiency

→ **required Quality outcome was not achieved.**

Harm

→ **injury, damage, or loss has occurred.**

A Quality deficiency can therefore exist without realized Harm.

Likewise, realized Harm should not automatically be attributed to a Quality deficiency merely because both exist.

Their connection must be supported through a credible Harm pathway.

They should therefore remain separate findings unless their connection is demonstrated through a Harm pathway.

10.2 Harm Potential Is Not Realized Harm

Harm potential and realized Harm describe different conditions.

Latent Harm potential exists at the level of the invariant Quality Factor or Quality Indicator within its applicable Core.

Its particular expression becomes identifiable in relation to an actual Quality Object and context.

Realized Harm exists only when injury, damage, or loss has actually occurred.

The distinction is:

latent Harm potential

→ **the invariant Quality Factor or Quality Indicator possesses a Harm-related nature;**

possible Harm

→ **a Harm pathway from a Harm-capable condition has been demonstrated;**

realized Harm

→ **injury, damage, or loss has occurred.**

The existence of latent Harm potential therefore does not mean that Harm exists or will occur.

Likewise, the identification of possible Harm does not mean that the Harm will become realized.

Realized Harm requires the Harm pathway to proceed under the necessary conditions of materialization.

Keeping these concepts distinct preserves the progression from latent Harm potential to its contextual expression and, where the necessary conditions occur, to realized Harm.

10.3 Risk Is Not Harm

Risk and Harm describe different things.

Harm is injury, damage, or loss.

Risk evaluates possible Harm through its probability and severity.

The distinction is:

Harm

→ **the injury, damage, or loss;**

Risk

→ **a determination based on the probability and severity of that Harm according to the Applicable Basis.**

Risk can therefore exist as a determination before Harm becomes realized.

Likewise, realized Harm does not by itself establish what the Risk was before the Harm occurred.

Risk determination requires consideration of probability and severity according to the Applicable Basis.

The occurrence or non-occurrence of Harm should therefore not be substituted for a Risk determination.

Risk and Harm should therefore remain separate findings.

10.4 Safety Is Not Quality

Safety and Quality are related, but they are not the same.

Quality concerns whether the required Quality outcome has been achieved.

Safety concerns whether the Risk associated with possible Harm is acceptable or tolerable according to the Applicable Basis.

The distinction is:

Quality

→ **achievement or non-achievement of the required Quality outcome;**

Safety

→ **evaluation of Risk against applicable Safety criteria.**

A Quality deficiency does not automatically establish that something is unsafe.

Likewise, a Safety determination does not establish that all required Quality outcomes have been achieved.

A Quality Object may therefore have a Quality deficiency while its associated Risk remains within applicable Safety criteria.

The two determinations may be connected through the Quality–Harm pathway, but neither replaces the other.

Safety and Quality should therefore remain separate determinations.

10.5 One Determination Cannot Automatically Substitute for Another

Quality, Harm, Risk, and Safety are connected, but each requires its own determination.

A finding in one area should not automatically be treated as a finding in another.

Therefore:

- a Quality deficiency does not automatically establish Harm;
- a Harm-capable condition does not automatically establish a Harm pathway or realized Harm;
- a Harm pathway does not automatically establish Risk;
- Risk does not automatically establish whether something is safe or unsafe; and
- a Safety determination does not automatically establish whether the required Quality outcome has been achieved.

Each determination answers a different question and requires the Evidence and Applicable Basis appropriate to that question.

The determinations can be connected where the required relationships are demonstrated.

Their relationship should remain traceable across the complete sequence:

Quality condition

→ possible Harm, where demonstrated

→ Risk, where determined

→ Safety determination, where applicable.

Keeping the determinations distinct prevents a conclusion reached for one purpose from being used as an unsupported conclusion for another.

This preserves the meaning and boundary of each determination.

11 Limits and Further Research

This Article establishes how Quality conditions, Harm, Risk, and Safety are methodologically connected while remaining distinct.

It does not establish that every Quality deficiency produces a Harm pathway or that every Harm pathway proceeds to realized Harm.

It also does not establish universal methods, scales, thresholds, or acceptance criteria for Risk or Safety.

These depend on the Applicable Basis and the particular context.

Further research is needed to test the framework across different classes of Quality Objects and different forms of Harm. Detailed testing is outside the scope of this Article.

In particular, further work should examine:

- how Harm pathways are identified and supported across different contexts;
- how different forms of Harm arise from Quality conditions;

- how uncertainty affects Harm and Risk determinations;
- how different Applicable Bases affect Risk and Safety determinations; and
- how the complete Quality–Harm pathway operates across independently developed Quality frameworks.

The next stage of the Quality and Harm research will test the proposed relationships through Support Service Quality Initiative (AMSI) and Infrastructure Quality Initiative (IQI) applications.

That testing will examine whether the pathway developed in this Article remains coherent across substantially different Quality Objects and contexts.

The results can then show where the methodology should be retained or refined. A subsequent article will separately examine the implications for Evidence Quality, uncertainty, Traceability, and Quality Determination.

12 Conclusion

Quality, Harm, Risk, and Safety are connected, but they are not interchangeable.

A Quality deficiency establishes that a required Quality outcome was not achieved.

Where a credible connection to possible injury, damage, or loss is demonstrated, the resulting Quality condition may be identified as Harm-capable.

Where the pathway is supported by Evidence, possible Harm can be identified.

Whether that Harm becomes realized depends on the conditions of materialization.

Risk adds the determination of probability and severity.

Safety evaluates that Risk against the applicable Safety criteria.

The complete relationship can therefore be expressed as:

Quality requirement

- **Evidence**
- **Quality Determination**
- **resulting Quality condition**
- **Harm-capable condition, where demonstrated**
- **Harm pathway, where demonstrated**
- **possible Harm**
- **probability and severity**
- **Risk**
- **applicable Safety criteria**
- **Safety determination.**

A related branch describes materialization:

Harm pathway

- **possible Harm**
- **conditions of materialization**
- **realized Harm, where those conditions occur.**

Each step requires the Evidence and Applicable Basis appropriate to the determination being made.

The framework therefore preserves two things at the same time:

- the distinction among Quality, Harm, Risk, and Safety; and
- the traceable relationships connecting them.

This provides the methodological basis for testing the Quality–Harm relationship across different Quality Objects and contexts.

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