



QUALITY CLAIM STANDARD — CORE

WHOLE QUALITY STANDARD WQI_QCC1

First Draft Edition — October 2026

Common Requirements for Determining the Quality
of a Quality Claim

WHOLE QUALITY INSTITUTE

Foreword

The Whole Quality Institute (WQI) develops a common methodology for determining Quality across different classes of Quality Objects while preserving the requirements, conditions, and methods that are specific to particular applications.

A Quality Claim communicates what has been established about the Quality State of a defined Quality Object. The original Quality Object and the Claim concerning it are separate Quality Objects for purposes of Quality Determination. A Claim may therefore have high Quality even when it communicates an unfavorable Quality State, provided that it responsibly communicates what has been established. Conversely, a Claim concerning a favorable Quality State may have poor Quality if it is unsupported, materially incomplete, inapplicable, or unintelligible.

WQI Foundational Article 16, From Quality Conditions to Claims — The Claim as a Quality Object, establishes the methodological basis for treating a Quality Claim as a separate Quality Object. Subsequent WQI research derives and tests the common Quality Factors and Quality Indicators used to determine the Quality of that Claim.

This Standard establishes that common Core.

The Core consists of four Quality Factors:

- Support;
- Material Sufficiency;
- Applicability; and
- Communicative Realization.

These Factors are examined through seven Quality Indicators:

- Substantive Support;
- Preservation of Material Relationships;
- Material Information Sufficiency;
- Recipient Applicability;
- Purpose Applicability;
- Context Applicability; and
- Intelligibility.

The Factors and Indicators provide the common structure for determining Claim Quality. They do not themselves establish every technical, legal, regulatory, professional, contractual, or domain-specific requirement that may apply to a Claim. Applicable Quality Outcome Criteria may be established by this Core where sufficiently invariant, by an applicable Context Guide, or by another justified application-specific basis.

Evidence Quality, Materiality, Uncertainty, Traceability, Boundary, Interfaces, Applicable Basis, Reference Layer, and Critical Conditions remain necessary parts of the determination where applicable. They support and constrain the determination of Claim Quality but are not additional Claim Quality Factors or Quality Indicators.

This Standard applies wherever a Quality Claim is treated as a Quality Object under the Whole Quality methodology. The Core may be applied directly. Where additional specificity is needed, an applicable Context Guide or another justified application-specific basis may establish Quality Outcome Criteria and other requirements for the particular class of Claims or application, provided that the invariant Core structure is preserved.

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1. Scope

This Standard establishes the common Core requirements for determining the Quality of a Quality Claim when the Claim is treated as a Quality Object under the Whole Quality methodology.

The Standard applies to Quality Claims concerning defined Quality Objects across different domains, applications, recipients, purposes, and Contexts. It establishes the invariant Quality Factors and Quality Indicators through which realization of the Intended Function of a Quality Claim is determined.

The Core establishes four Quality Factors:

- Support;
- Material Sufficiency;
- Applicability; and
- Communicative Realization.

These Factors are examined through seven Quality Indicators:

- Substantive Support;
- Preservation of Material Relationships;
- Material Information Sufficiency;
- Recipient Applicability;
- Purpose Applicability;
- Context Applicability; and
- Intelligibility.

Application of this Standard shall begin by defining the Quality Claim that is to be treated as the Quality Object. The determination shall identify the Claim's Intended Function, relevant Intended Results, Boundary and Interfaces, recipient, purpose, Context, Applicable Basis, applicable Quality Outcome Criteria, and Methodological Resolution. The applicable Quality Outcome Criteria may be established by this Core, an applicable Context Guide, or another justified application-specific basis.

The Standard applies to the Quality of the Claim itself. It does not replace or repeat the Quality Determination of the original Quality Object about which the Claim is made.

The Quality State of the original Quality Object and the Quality State of the Claim are distinct. Accordingly, the favorability or unfavorability of a Finding or Conclusion concerning the original Quality Object does not by itself determine the Quality of the Claim communicating that Finding or Conclusion.

This Standard does not require one complete universal set of Quality Outcome Criteria for all Quality Claims. It also does not establish universal numerical scores, Factor or Indicator weightings, acceptance thresholds, communication formats, technical methods, legal requirements, regulatory requirements, professional requirements, or certification requirements. This Core may establish a Quality Outcome Criterion where that criterion is sufficiently invariant across the relevant class of Quality Claims.

Additional or more specific requirements, including applicable Quality Outcome Criteria, may be established through Context Guides or another justified application-specific basis consistent with the Applicable Basis and Reference Layer, where applicable.

The Core Factors and Indicators shall remain invariant unless revised through controlled WQI methodological revision. Their application, Evidence, Quality Outcome Criteria, Critical Conditions, and methods of determination may vary according to the defined Quality Claim, its Intended Function, recipient, purpose, Context, Applicable Basis, and Methodological Resolution.

This Standard provides the common methodological basis for determining Claim Quality. It may be applied directly or through Context Guides and other application-specific WQI documents that preserve the Core structure.

2. Normative Framework

The Quality of a Quality Claim shall be determined by treating the Claim as a defined Quality Object in its own right. The determination shall identify the Claim's Intended Function, Intended Results, Boundary, Interfaces, Context, Applicable Basis, and applicable Quality Outcome Criteria. Those Quality Outcome Criteria may be established by this Core, an applicable Context Guide, or another justified application-specific basis.

The determination shall distinguish the Quality Claim from the original Quality Object about which the Claim is made. The two Quality Objects are related through the Findings and other information supporting the Claim, but each has its own Quality State and may be subject to a separate Quality Determination.

The normative framework established in this section defines the basis within which the Quality Factors and Quality Indicators of this Standard shall be applied.

2.1 Quality Claim as a Quality Object

A Quality Claim shall be treated as a Quality Object when its Quality is being determined under this Standard.

The Quality Claim and the original Quality Object shall remain distinct.

The original Quality Object has an actual Quality State that exists independently of the Claim. Quality Determination concerning that object establishes, through Evidence and applicable Quality Outcome Criteria, what can be established about that Quality State through Evidence-Supported Findings.

A Quality Claim is subsequently formed from the applicable Findings through Materiality and Synthesis of Material Findings and, where applicable, expression of a Conclusion or Refusal to Express a Conclusion.

The Claim does not create, replace, or modify the Quality State of the original Quality Object. Nor does treatment of the Claim as a Quality Object constitute a redetermination of the Quality State of the original Quality Object.

When the Claim is treated as a Quality Object, it has its own Quality State. That Quality State concerns the actual Quality-relevant condition of the Claim in relation to realization of the Claim's Intended Function and Intended Results.

Accordingly, determination of Claim Quality shall address the Claim itself, including whether it preserves the supportable meaning of the applicable Findings, provides materially sufficient information, applies to its intended recipient, purpose, and Context, and communicates intelligibly.

A favorable Quality State of the original Quality Object does not establish favorable Quality of the Claim. An unfavorable Quality State of the original Quality Object does not establish unfavorable Quality of the Claim.

A Claim may therefore realize its Intended Function while responsibly communicating unfavorable Findings or a Negative Conclusion concerning the original Quality Object. Conversely, a Claim may fail to realize its Intended Function even where the original Quality Object has a favorable Quality State.

The Evidence, Findings, Synthesis, Conclusion or Refusal, and Traceability connecting the original Quality Determination to the Claim may form part of the basis for determining Claim Quality, but they shall not be treated as though the original Quality Object and the Claim were a single Quality Object.

2.2 Intended Function

The Quality of a Quality Claim shall be determined in relation to the Intended Function of the Claim.

At the general level, the Intended Function of a Quality Claim is to provide its recipient with a supportable and materially sufficient communication of what has been established about the Quality State of the original Quality Object, for the purpose and within the Context for which the Claim is made.

This general Intended Function applies to Quality Claims as a class of Quality Objects and provides the functional basis for the Quality Factors and Quality Indicators established by this Standard.

Determination of Function Realization shall examine whether the Claim:

- remains supportable by the applicable Evidence-Supported Findings;
- preserves material relationships necessary to communicate the supportable meaning of those Findings;
- provides the material information necessary for the Claim to perform its Intended Function;
- applies to the intended recipient;
- applies to the purpose for which the Claim is made;
- applies within the relevant Context; and
- communicates intelligibly for its intended use.

The Intended Function of a Quality Claim shall not be interpreted as requiring communication of all available Evidence, Findings, records, or supporting information. The information required shall be determined by Materiality in relation to the Claim's Intended Function, recipient, purpose, Context, Applicable Basis, and the applicable Quality Outcome Criteria.

The Intended Function shall not permit the Claim to exceed what the applicable Findings can support. Recipient needs, intended purpose, or Context may affect what information is material and how that information is communicated, but they shall not expand the substantive support available for the Claim.

The favorability of the information communicated is not a requirement of the Intended Function. Function Realization concerns whether the Claim responsibly communicates what has been established, not whether the established Quality State of the original Quality Object is favorable or unfavorable.

The general Intended Function established in this section shall provide the common functional reference for application of the four Quality Factors and seven Quality Indicators of this Standard.

2.3 Specific Intended Function

A particular Quality Claim may have a Specific Intended Function within the general Intended Function established in 2.2.

The Specific Intended Function shall identify the particular informational function the Claim is intended to perform for its recipient, purpose, and Context.

A Specific Intended Function may concern, for example, communication supporting a purchasing decision, conformity determination, operational decision, regulatory or contractual use, assessment result, financing or insurance decision, service decision, or other defined use.

The Specific Intended Function shall remain consistent with the general Intended Function of a Quality Claim. It shall not permit a Claim to exceed, alter, or otherwise misrepresent what the applicable Evidence-Supported Findings can support.

The Specific Intended Function shall be used, where applicable, to determine:

- what information is material to the Claim;
- which recipient requirements are relevant;
- the purpose for which the Claim must be applicable;
- the Context within which the Claim must function;
- the applicable Quality Outcome Criteria;
- relevant Critical Conditions; and
- the form and level of communication necessary for the Claim to realize its Intended Function.

Different Quality Claims arising from the same body of Findings may have different Specific Intended Functions. Differences in recipient, purpose, or Context may therefore justify differences in material content, emphasis, level of detail, or form of communication.

Such differences shall not justify substantive inconsistency with the applicable Findings or omission, distortion, or alteration of information or material relationships necessary for the Claim to remain supportable and materially sufficient.

Where no narrower Specific Intended Function is established, the general Intended Function in 2.2 shall govern the determination.

A requirement arising solely from a particular Specific Intended Function shall not be treated as an invariant requirement for all Quality Claims unless it is independently established as part of the common Core.

2.4 Boundary and Interfaces

The Quality Claim shall have a defined Boundary sufficient to identify what constitutes the Claim for the purposes of Quality Determination.

The Boundary shall identify the information communicated directly as part of the Claim and, where applicable, material supporting information made available through defined Interfaces.

Material supporting information may be provided through an Interface rather than reproduced within the Claim where that mode of access is consistent with the Claim's Intended Function, recipient, purpose, Context, Applicable Basis, and applicable Quality Outcome Criteria.

Use of an Interface shall not reduce the requirement for Material Information Sufficiency. Information necessary for the Claim to realize its Intended Function shall remain available and accessible to the extent required by the applicable Quality Outcome Criteria.

Interfaces may connect the Claim to matters outside its Boundary, including:

- the original Quality Object;
- the applicable Evidence-Supported Findings;
- supporting Evidence;
- the Synthesis of Material Findings;
- the applicable Conclusion or Refusal to Express a Conclusion, where applicable;
- the claimant or other attributable source;
- the intended recipient;
- the Applicable Basis and Reference Layer;
- supporting information concerning Harm, Risk, or Safety, where material to the Claim;
- supporting records or referenced information; and
- communication systems or other dependencies necessary for access to or use of the Claim.

An Interface shall not be treated as part of the Claim merely because it is connected to the Claim. Its relevance to Claim Quality shall be determined by the function it performs in relation to the Claim's Intended Function and applicable Quality Outcome Criteria.

Where realization of the Claim's Intended Function depends materially on an Interface, that dependency shall be identified and shall remain sufficiently visible for the determination.

A failure, limitation, change, or loss of an Interface may affect Claim Quality where it causes the Claim to become unsupported, materially insufficient, inapplicable, unintelligible, or otherwise unable to realize its Intended Function.

The Boundary and Interfaces used for the determination shall be defined at a Methodological Resolution sufficient to prevent material information, dependencies, or limitations from being excluded merely by defining the Claim too narrowly.

The Boundary and Interfaces of the Quality Claim shall remain distinct from the Boundary and Interfaces of the original Quality Object, although relationships between them may be relevant to Traceability and determination of Claim Quality.

2.5 Applicable Basis and Reference Layer

Determination of the Quality of a Quality Claim shall identify the Applicable Basis relevant to the Claim and its Intended Function.

The Applicable Basis establishes or justifies what applies to the Quality Claim and its determination. It may include, as applicable, laws, regulations, standards, contractual requirements, professional requirements, technical or methodological requirements, defined recipient requirements, applicable Context Guides, and other justified sources relevant to the Claim.

The Applicable Basis for the Quality Claim shall be distinguished from the Applicable Basis for the original Quality Object.

The two may overlap, and requirements applicable to the original Quality Object may be material to the Claim. However, requirements governing the condition or performance of the original Quality Object do not automatically establish the requirements governing the Quality of the Claim that communicates what has been established about that object.

The Applicable Basis for the Claim shall be used, where relevant, together with this Core, an applicable Context Guide, or another justified application-specific basis, to establish or justify:

- applicable Quality Outcome Criteria;
- requirements concerning the Claim's recipient, purpose, and Context;
- requirements concerning material information;
- requirements concerning the form, content, accessibility, or intelligibility of communication;
- requirements concerning attribution;
- requirements concerning Traceability;
- applicable Critical Conditions; and
- requirements concerning information about Harm, Risk, or Safety where such information is material to realization of the Claim's Intended Function.

The Reference Layer shall identify the sources used to establish or justify applicable Quality Outcome Criteria and other requirements relevant to the determination, including contextual or application-specific criteria where applicable.

The Reference Layer may include multiple sources where no single source provides the complete applicable basis for the Claim. The relevance, authority, applicability, and relationship of those sources shall be sufficiently established for the intended determination.

The Reference Layer shall not itself be treated as Evidence of the actual Quality State of the Claim. Requirements and criteria establish or justify what applies; Evidence supports Findings concerning the actual condition of the Claim. These functions shall remain distinct.

The Applicable Basis and Reference Layer may vary among different Quality Claims according to the original Quality Object, Specific Intended Function, recipient, purpose, Context, jurisdiction, contractual arrangement, professional setting, or other applicable conditions.

Such variation shall not alter the invariant Quality Factors and Quality Indicators established by this Core.

Where the Applicable Basis or Reference Layer is incomplete, conflicting, uncertain, or otherwise limited in a manner material to the determination, that limitation shall remain visible and shall be addressed through the applicable Quality Outcome Criteria, Findings, Uncertainty, Critical Conditions, or other appropriate part of the determination.

No requirement shall be treated as applicable to a Quality Claim solely because it is available within the Reference Layer. Its applicability to the defined Claim and determination shall be established or justified.

3. Application of the Core

3.1 General

Application of this Core shall determine what can be established about the Quality State of a defined Quality Claim through the four Quality Factors and seven Quality Indicators established in Section 4.

The determination shall begin with the Quality Claim as the defined Quality Object and shall identify, to the extent applicable:

- the Claim's general and Specific Intended Function;
- relevant Intended Results;
- the recipient;
- the purpose for which the Claim is made;
- the relevant Context;
- the Claim's Boundary and material Interfaces;
- the Applicable Basis and Reference Layer;
- the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis;
- relevant Critical Conditions; and
- the Methodological Resolution of the determination.

Application of the Core shall keep two determinations distinct: the Quality Determination concerning the original Quality Object and the Quality Determination concerning the Quality Claim itself.

Findings established through Quality Determination of the original Quality Object may provide the substantive basis from which the Claim is formed. Determination of Claim Quality shall not redetermine those Findings merely because the Claim is being examined as a separate Quality Object.

Determination of Claim Quality shall instead examine whether the Claim realizes its own Intended Function, including whether it is supportable, materially sufficient, applicable to its intended recipient, purpose, and Context, and intelligible.

The Claim-quality determination shall use Evidence concerning the actual condition of the Claim. Depending on the Claim and its Intended Function, that Evidence may include the Claim itself; information concerning its formation; the original-object Findings on which it relies; material relationships; attribution; supporting information; Interfaces; communication conditions; and other matters needed to determine realization of the applicable Claim Quality Factors and Quality Indicators.

Where information concerning Harm, Risk, or Safety is material to realization of the Claim's Intended Function, its presence, omission, treatment, or accessibility shall be examined as part of the applicable Claim Quality determination. Quality, Harm, Risk, and Safety shall remain distinct.

The Claim-quality determination shall account for Materiality and Uncertainty. It shall also preserve sufficient Traceability from the applicable basis and Evidence, through the Evidence-Supported Findings and Synthesis of Material Findings, to the resulting Claim-quality Conclusion or Refusal to Express a Conclusion.

The four Quality Factors and seven Quality Indicators shall be applied as an integrated Core. Interaction among them shall not be interpreted as making one Factor or Indicator a substitute for another.

Strength in one Factor or Indicator shall not, by itself, compensate for material non-realization of another necessary Factor or Indicator.

Application of the Core shall not require universal numerical scoring, weighting, averaging, or grading. The significance of Findings and the effect of limitations shall be determined in relation to the defined Claim, its Intended Function, applicable Quality Outcome Criteria, Materiality, Critical Conditions, and Methodological Resolution.

The resulting determination shall state only what the available Evidence and applicable Findings responsibly support.

3.2 Harm, Risk, and Safety Information

Information concerning Harm, Risk, or Safety may be material to realization of the Intended Function of a Quality Claim.

Where such information is material, the Claim shall communicate it directly or provide appropriate access to it through a defined Interface, to the extent required by the applicable Context Guide, Applicable Basis, and applicable Quality Outcome Criteria.

Such information may concern, where applicable:

- an identified Harm-capable condition;
- a Harm pathway;
- Possible Harm;
- Conditions of Materialization;
- Realized Harm;
- a Risk determination;
- a Safety determination; and
- material limitations or Uncertainty associated with those matters.

Quality, Harm, Risk, and Safety shall remain distinct.

A Quality condition does not by itself establish Harm. Identification of Possible Harm does not by itself establish Risk. Risk requires determination of the probability and severity of Possible Harm according to the Applicable Basis. Safety concerns whether Risk is acceptable or tolerable according to applicable Safety criteria.

Accordingly, information concerning Harm, Risk, or Safety shall not be treated as a substitute for determination of the Quality of the Claim, and determination of Claim Quality shall not be treated as a substitute for a Harm, Risk, or Safety determination.

The absence of Realized Harm shall not by itself establish Safety, and identification of Possible Harm shall not by itself establish that a condition is unsafe.

Where material Harm, Risk, or Safety information is maintained outside the Boundary of the Claim, the Claim shall provide a sufficiently defined and usable Interface to that information where such access is necessary for realization of the Claim's Intended Function.

The Claim shall preserve material distinctions, relationships, conditions, limitations, and Uncertainty associated with Harm, Risk, or Safety information where their loss could change the supportable meaning or use of the Claim.

The omission, obscuring, distortion, or loss of necessary access to material Harm, Risk, or Safety information may constitute non-realization of Material Sufficiency, Applicability, Communicative Realization, Support, or another applicable requirement of this Standard.

This Core does not establish universal Harm, Risk, or Safety criteria, scales, thresholds, or methods. Where such criteria or methods are required, they shall be established through the applicable Context Guide, Applicable Basis, Reference Layer, or other justified application-specific source.

3.3 Evidence and Evidence Quality

Determination of the Quality of a Quality Claim shall be Evidence-based.

Evidence used in the determination shall concern the actual condition of the Claim as the defined Quality Object and shall be sufficient to support the Findings required for the intended determination.

Evidence concerning Claim Quality may include, where applicable:

- the content and form of the Claim;
- the applicable Evidence-Supported Findings concerning the original Quality Object;

- information necessary to establish the relationship between those Findings and the Claim;
- information concerning the preservation of material relationships;
- material supporting information communicated directly or made available through defined Interfaces;
- information concerning the recipient, purpose, and Context of the Claim;
- information concerning the operation, availability, or limitations of material Interfaces; and
- other Evidence necessary to determine realization of the applicable Quality Factors and Quality Indicators.

Evidence concerning the Quality Claim shall be distinguished from the Evidence used to determine the Quality State of the original Quality Object.

Evidence from the original Quality Determination may remain relevant to Claim Quality where it is necessary to establish the supportability, meaning, limitation, or Traceability of the Claim. Its use in determining Claim Quality does not constitute a redetermination of the original Quality Object.

Evidence shall not be treated as equivalent to an Evidence-Supported Finding. A Finding states what the applicable Evidence can responsibly establish about the actual condition of the Claim.

The scope of a Finding concerning Claim Quality shall not exceed what the applicable Evidence can support.

Where Evidence is relied upon for determination of Claim Quality, its Evidence Quality shall be adequate for the Finding and Methodological Resolution for which it is used.

Evidence Quality shall be considered through the applicable WQI Evidence Quality requirements, including the extent and detail of the necessary Evidence, the trustworthiness of its representation, and its applicability to the subject, Context, and determination for which it is used.

High-quality Evidence does not by itself establish favorable Claim Quality. It establishes a stronger basis for determining what can responsibly be found about the Claim. Conversely, limited Evidence Quality shall not automatically be interpreted as Evidence that the actual Quality State of the Claim is unfavorable.

Where Evidence Quality limitations materially constrain what can be established about the Claim, those limitations and resulting Uncertainty shall remain visible and shall bound the Findings, Synthesis, Conclusion, or Quality Claim concerning the Claim as appropriate.

Evidence Quality is therefore a necessary supporting condition of Claim Quality Determination but is not an additional Claim Quality Factor or Quality Indicator under this Core.

3.4 Materiality

Materiality shall be considered in determining the Quality of a Quality Claim.

Materiality concerns the significance of a Finding, condition, relationship, limitation, or other matter to the Synthesis, Conclusion, or information necessary for the Quality Claim to realize its Intended Function for its recipient.

Materiality shall be determined in relation to the defined Claim, its Intended Function and Intended Results, recipient, purpose, Context, Applicable Basis, applicable Quality Outcome Criteria, and Methodological Resolution.

Materiality shall be used to determine, as applicable:

- which Findings concerning the original Quality Object are necessary to the Claim;
- which relationships among Findings, conditions, limitations, and other information must be preserved;
- which supporting information must be communicated directly or made appropriately accessible through an Interface;
- which limitations, qualifications, conditions, and Uncertainty must remain visible;

- whether information concerning Harm, Risk, or Safety is necessary to realization of the Claim's Intended Function;
- which Findings concerning the Quality of the Claim require consideration in Synthesis; and
- which matters may materially constrain the permissible Conclusion or require Refusal to Express a Conclusion.

Materiality does not require inclusion of all available Evidence, Findings, records, or supporting information. Information that is not material to realization of the Claim's Intended Function need not be included solely because it is available.

Conversely, brevity, communication format, recipient preference, or practical convenience shall not justify omission, obscuring, or distortion of information that is material to realization of the Claim's Intended Function.

Materiality may vary among Claims arising from the same original Quality Determination where those Claims have different recipients, purposes, Contexts, or Specific Intended Functions. Such variation shall not permit a Claim to exceed what the applicable Evidence-Supported Findings can support.

Materiality shall not be used to convert an unsupported matter into a supported one. It determines the significance of a matter to the Claim and its determination; it does not create Evidence, establish a Finding, or expand the substantive support available for the Claim.

Where the materiality of a matter cannot be determined with sufficient support, the resulting limitation or Uncertainty shall remain visible and shall be addressed at the Methodological Resolution appropriate to the determination.

3.5 Uncertainty

Uncertainty relevant to determination of the Quality of a Quality Claim shall remain visible to the extent material to the determination or to realization of the Claim's Intended Function.

Uncertainty concerns what remains not fully known, resolved, or determinable. It may arise from limitations in Evidence or Evidence Quality, unresolved conditions or relationships, limitations in the Applicable Basis or Reference Layer, limitations of material Interfaces, Methodological Resolution, or other matters relevant to the Claim or its determination.

Uncertainty shall be distinguished from an unfavorable Quality condition.

The presence of Uncertainty does not by itself establish that the Claim has an unfavorable Quality State. Conversely, the absence of identified Uncertainty does not by itself establish favorable Claim Quality.

Where Uncertainty affects what can responsibly be established about the Claim, it shall bound the applicable Evidence-Supported Findings.

Where Uncertainty is material to the content or use of the Claim, the Claim shall communicate that Uncertainty or provide appropriate access to it through a defined Interface to the extent required for realization of the Claim's Intended Function.

Where Uncertainty concerns Harm, Risk, or Safety information that is material to the Claim, that Uncertainty shall remain visible at the level to which it applies.

Uncertainty concerning a Harm-capable condition, Harm pathway, Possible Harm, Conditions of Materialization, or Realized Harm may affect what can responsibly be established or communicated about Harm. Uncertainty concerning the probability or severity of Possible Harm may affect a Risk determination. Uncertainty concerning Risk may, in turn, affect a Safety determination made according to applicable Safety criteria.

Uncertainty at one stage shall not be resolved merely by proceeding to a later stage. A Risk or Safety statement shall not communicate greater certainty than is supported by the underlying Harm and Risk information on which it depends.

Uncertainty shall not be removed, concealed, or reduced in communication beyond what the applicable Evidence and Findings support.

The treatment of Uncertainty shall consider, as applicable:

- the source and nature of the Uncertainty;
- the part of the Claim or determination affected;
- the significance of the Uncertainty to the applicable Findings;
- whether the Uncertainty affects Substantive Support or preservation of material relationships;
- whether the Uncertainty constitutes material information necessary to the Claim;
- whether it affects Recipient, Purpose, or Context Applicability;
- whether it affects the intelligible use or interpretation of the Claim;
- whether it concerns material Harm, Risk, or Safety information; and
- whether it materially constrains the permissible Synthesis, Conclusion, or Quality Claim concerning the Claim.

Uncertainty concerning future fulfillment of a condition shall not be treated as Evidence that the condition will or will not be fulfilled.

Where a Positive Conclusion cannot responsibly be supported because of material Uncertainty, the determination shall consider whether the available Findings support a Conditionally Positive Conclusion, a Negative Conclusion on an affirmative evidentiary basis, or Refusal to Express a Conclusion in accordance with Section 5.

Insufficient Evidence, an Evidence gap, or unresolved Uncertainty shall not by itself constitute the affirmative basis required for a Negative Conclusion.

Uncertainty shall therefore constrain what may responsibly be established or communicated without being treated as a separate Claim Quality Factor or Quality Indicator under this Core.

3.6 Traceability

Traceability shall be maintained to the extent necessary to understand and support the Quality Determination of a Quality Claim.

Traceability shall make visible the material relationships connecting the Claim and its determination to their relevant methodological and evidentiary basis.

As applicable, Traceability shall permit the material path to be followed among:

- the defined Quality Claim as the Quality Object;
- the Claim's Intended Function and relevant Intended Results;
- the recipient, purpose, and Context;
- the Applicable Basis and Reference Layer;
- applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis;
- the applicable Evidence and Evidence Quality;
- Evidence-Supported Findings concerning the original Quality Object that provide substantive support for the Claim;
- Materiality and the Synthesis of Material Findings from which the Claim was formed;
- the applicable Conclusion or Refusal to Express a Conclusion concerning the original Quality Object, where applicable;
- material limitations and Uncertainty;
- material Harm, Risk, or Safety information, where applicable;
- material Interfaces and supporting information outside the Claim's Boundary;
- Evidence-Supported Findings concerning the Quality of the Claim itself; and
- the Synthesis and resulting Conclusion or Refusal to Express a Conclusion concerning the Quality of the Claim.

Traceability shall preserve the distinction between the determination concerning the original Quality Object and the determination concerning the Quality Claim as a separate Quality Object.

Accordingly, Traceability shall not be interpreted as requiring the two determinations to be merged into a single determination.

Where Harm, Risk, or Safety information is material to the Claim, Traceability shall be sufficient to follow the material relationships among the relevant Quality condition, Harm-capable condition or Harm information, Risk determination, Safety determination, applicable criteria, supporting Evidence, and material Uncertainty, to the extent those relationships are applicable to the Claim.

Traceability shall not imply that Quality, Harm, Risk, and Safety are a single determination or that establishment of one automatically establishes another.

Traceability may be provided through information contained within the Claim or through defined Interfaces to supporting records, Findings, criteria, determinations, or other information outside the Claim's Boundary.

Use of an Interface shall not break the material Traceability necessary for the Claim or its Quality Determination to be understood and, where appropriate, reviewed.

Traceability does not establish the truth, accuracy, sufficiency, validity, or Quality of the information to which it provides a path. A fully traceable Claim may still be unsupported, materially insufficient, inapplicable, unintelligible, or otherwise unable to realize its Intended Function.

Conversely, absence or limitation of Traceability may constrain what can responsibly be established about Claim Quality where the material basis of the Claim or its determination cannot be sufficiently followed or understood.

The extent and detail of Traceability required shall correspond to the Claim's Intended Function, recipient, purpose, Context, Applicable Basis, applicable Quality Outcome Criteria, Materiality, and Methodological Resolution.

Traceability supports the determination of Claim Quality but is not an additional Claim Quality Factor or Quality Indicator under this Core.

3.7 Critical Conditions

Critical Conditions relevant to the Quality of a Quality Claim shall be identified and applied where their absence, non-achievement, violation, failure, or unresolved status would prevent a responsible Positive Conclusion or otherwise materially constrain the permissible Conclusion or Quality Claim.

Critical Conditions shall be established through the applicable Context Guide, Applicable Basis, applicable Quality Outcome Criteria, or other justified application-specific basis. This Core does not establish universal Critical Conditions for all Quality Claims.

A Critical Condition may relate, as applicable, to:

- Substantive Support for the Claim;
- preservation of a material relationship necessary to retain the supportable meaning of the applicable Findings;
- availability of material information necessary for the Claim to realize its Intended Function;
- Recipient, Purpose, or Context Applicability;
- Intelligibility necessary for the intended use of the Claim;
- a material Interface or dependency necessary for access to or use of the Claim;
- a material limitation or Uncertainty that constrains what can responsibly be established or communicated;
- material information concerning Harm, Risk, or Safety; or
- another condition established as critical through the applicable Context Guide, Applicable Basis, or applicable Quality Outcome Criteria.

A Critical Condition shall not be inferred solely from the importance of a subject. Its critical status shall be established or justified in relation to the defined Claim, its Intended Function, recipient, purpose, Context, Applicable Basis, applicable Quality Outcome Criteria, and Methodological Resolution.

Failure or unresolved status of a Critical Condition shall not automatically establish a Negative Conclusion.

Where a Critical Condition is not achieved, is violated, has failed, or remains unresolved, the determination shall examine what the applicable Evidence-Supported Findings establish and how the condition constrains the permissible Synthesis and Conclusion.

A Negative Conclusion shall require an affirmative evidentiary basis for non-realization. Where the available basis instead prevents a responsible Positive, Conditionally Positive, or Negative Conclusion, Refusal to Express a Conclusion may be required.

Where a Critical Condition concerns Harm, Risk, or Safety, its treatment shall preserve the distinction among those concepts. Failure of a Quality-related Critical Condition shall not by itself establish Harm, Risk, or Safety, and a Harm-, Risk-, or Safety-related Critical Condition shall be interpreted according to its applicable criteria and basis.

Material Uncertainty affecting a Critical Condition shall remain visible. Uncertainty shall not be treated as resolution of the Critical Condition in either a favorable or unfavorable direction beyond what the Evidence supports.

Critical Conditions may interact with multiple Quality Factors or Quality Indicators. Such interaction does not make a Critical Condition an additional Claim Quality Factor or Quality Indicator.

The identification, basis, status, and effect of each material Critical Condition shall remain sufficiently Traceable for the resulting Quality Determination to be understood and, where appropriate, reviewed.

4. Quality Factors and Quality Indicators

4.1 General

The Quality of a Quality Claim shall be determined through the Quality Factors and Quality Indicators established by this Core.

The Quality Factors represent principal dimensions of Function Realization through which what can be established about the Quality State of the Claim is determined.

This Core establishes four Quality Factors:

- Support;
- Material Sufficiency;
- Applicability; and
- Communicative Realization.

The Quality Factors are examined through seven Quality Indicators:

Support

- Substantive Support; and
- Preservation of Material Relationships.

Material Sufficiency

- Material Information Sufficiency.

Applicability

- Recipient Applicability;
- Purpose Applicability; and
- Context Applicability.

Communicative Realization

- Intelligibility.

The four Quality Factors and seven Quality Indicators constitute the invariant Core structure for determining the Quality of a Quality Claim at the present WQI Methodological Resolution.

The Factors and Indicators shall be applied in relation to the defined Claim, its Intended Function and relevant Intended Results, recipient, purpose, Context, Boundary and Interfaces, Applicable Basis, and applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

The Factors and Indicators identify the dimensions of Claim Quality that must be examined. This Core does not require one complete universal set of Quality Outcome Criteria for every application. It also does not establish universal methods, thresholds, numerical scores, weightings, communication formats, or context-specific Critical Conditions. Those matters shall be established only where required by this Core, an applicable Context Guide, or another justified application-specific basis.

Additional or more specific requirements shall be established, where applicable, through Context Guides or another justified application-specific basis consistent with the Applicable Basis and Reference Layer.

The Factors and Indicators are distinct but may interact. A condition affecting one Factor or Indicator may also affect another, and a single item of Evidence may support Findings relevant to more than one Factor or Indicator.

Interaction shall not make the Factors or Indicators interchangeable. Material non-realization of one necessary Factor or Indicator shall not be presumed to be compensated for by stronger realization of another.

Evidence Quality, Materiality, Uncertainty, Traceability, Critical Conditions, and information concerning Harm, Risk, or Safety may materially affect application of the Factors and Indicators. They shall be treated according to their respective functions and shall not be treated as additional Claim Quality Factors or Quality Indicators.

The favorability or unfavorability of the Quality State of the original Quality Object shall not determine the realization of these Factors or Indicators. Their application concerns whether the Claim itself realizes its Intended Function as a separate Quality Object.

The Factors and Indicators established by this Core shall remain invariant across Claim Contexts unless revised through controlled WQI methodological revision. Their application, Quality Outcome Criteria, Evidence, Critical Conditions, and methods of determination may vary according to the particular class and Context of Quality Claim.

4.2 Support

Support is the Quality Factor concerning whether the Quality Claim remains within and preserves the supportable meaning of what has been established about the Quality State of the original Quality Object.

Support shall be determined through two Quality Indicators:

- Substantive Support; and
- Preservation of Material Relationships.

A Claim realizes Support where its substantive content remains supportable by the applicable Evidence-Supported Findings and where the material relationships necessary to preserve the meaning of those Findings are maintained.

Support concerns more than the accuracy of individual statements considered separately. A Claim may reproduce individual Findings accurately while changing their collective meaning through omission, separation, rearrangement, qualification, emphasis, or other treatment of material relationships.

Support therefore requires consideration of both:

- whether what the Claim communicates is substantively supported; and
- whether the material relationships necessary to retain the supportable meaning of what has been established are preserved.

The Claim shall not assert more than the applicable Findings establish, increase certainty beyond what those Findings support, change the applicable scope or conditions of a Finding, or otherwise communicate a substantive meaning that exceeds or alters the determined basis.

Where the Claim communicates a Conclusion or Refusal to Express a Conclusion concerning the original Quality Object, that communication shall remain consistent with the applicable Synthesis of Material Findings and the basis supporting that Conclusion or Refusal.

Material Uncertainty, limitations, conditions, and qualifications shall be considered under Support where their alteration, concealment, or removal would cause the Claim to communicate a meaning or degree of certainty that the applicable Findings do not support.

Where information concerning Harm, Risk, or Safety forms part of the Claim, Support shall preserve the distinctions and material relationships necessary to prevent the Claim from communicating a Harm, Risk, or Safety determination beyond what the applicable basis supports.

Support does not require all Evidence, Findings, or supporting records to be reproduced within the Claim. Supporting information may remain outside the Claim's Boundary where appropriate Interfaces and Traceability permit the material basis of the Claim to be followed to the extent required by the applicable Quality Outcome Criteria.

Support shall be distinguished from Material Sufficiency. Support concerns whether the substantive meaning communicated by the Claim remains within and preserves what has been established. Material Sufficiency concerns whether the information necessary for the Claim to realize its Intended Function is communicated or appropriately accessible.

A Claim may therefore be substantively supportable yet materially insufficient, or may contain extensive information while communicating assertions or relationships that are not substantively supported.

Support shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.2.1 Substantive Support

Substantive Support is the Quality Indicator concerning whether the substantive content of a Quality Claim remains within what the applicable Evidence-Supported Findings concerning the original Quality Object can support.

The Claim shall not communicate a substantive assertion, qualification, level of certainty, scope, condition, or Conclusion that exceeds or materially alters what the applicable Findings establish.

Substantive Support shall consider, as applicable, whether the Claim:

- communicates assertions that are supported by the applicable Findings;
- preserves the scope and conditions under which those Findings apply;
- preserves qualifications and limitations that materially constrain what can be established;
- does not communicate a greater degree of certainty than the applicable Findings support;
- distinguishes established Findings from matters that remain uncertain or unresolved;
- preserves the substantive basis for a Conclusion or Refusal to Express a Conclusion concerning the original Quality Object; and
- does not transform absence of sufficient support into an affirmative Finding that the available Evidence does not establish.

Where a Claim communicates a Positive, Conditionally Positive, or Negative Conclusion concerning the original Quality Object, the expressed Conclusion shall remain supportable by the applicable Synthesis of Material Findings.

Where the applicable basis supports only Refusal to Express a Conclusion, the Claim shall not communicate a substantive Conclusion as though one had been established.

A Conditionally Positive Conclusion shall preserve the identified material future condition or conditions upon which the Positive Conclusion depends. It shall not communicate or imply that fulfillment of those conditions has already occurred or will occur.

A Negative Conclusion shall require an affirmative evidentiary basis for non-realization. Inability to support a Positive Conclusion, insufficient Evidence, an Evidence gap, or unresolved Uncertainty shall not by itself be communicated as establishing a Negative Conclusion.

Where Harm, Risk, or Safety information is communicated, the Claim shall not state or imply a Harm, Risk, or Safety determination beyond what the applicable Findings and relevant determination support. In particular, identification of a Quality condition shall not by itself be communicated as establishing Harm; Possible Harm shall not by itself be communicated as establishing Risk; and Risk shall not by itself be communicated as establishing Safety or lack of Safety without application of the relevant Safety criteria.

Substantive Support does not require reproduction of all Evidence or Findings within the Claim. The supporting basis may remain outside the Claim's Boundary where sufficient Traceability and appropriate Interfaces permit the substantive support for the Claim to be established as required by the applicable Quality Outcome Criteria.

A Claim shall not be considered substantively supported merely because its individual statements are factually supportable when their combination, qualification, emphasis, or presentation produces an overall substantive assertion that the applicable Findings do not support.

Substantive Support shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.2.2 Preservation of Material Relationships

Preservation of Material Relationships is the Quality Indicator concerning whether a Quality Claim maintains the relationships among Findings, conditions, limitations, Uncertainty, and other material information that are necessary to preserve the supportable meaning of what has been established about the original Quality Object.

Individual statements may remain substantively supportable when considered separately while their combined communication produces a meaning that the applicable Findings do not support.

The Claim shall therefore preserve material relationships necessary to understand what the applicable Findings collectively establish.

Such relationships may include, as applicable:

- a Finding that depends upon or is qualified by another Finding;
- a Finding that applies only under identified conditions or within a defined scope;
- relationships between favorable and unfavorable Findings;
- relationships between Findings and material limitations or Uncertainty;
- relationships between Findings and applicable Critical Conditions;
- relationships among Materiality, Synthesis of Material Findings, and the applicable Conclusion or Refusal to Express a Conclusion, where applicable;
- temporal relationships necessary to distinguish past, present, or future conditions;
- causal, conditional, sequential, or other relationships where their preservation is necessary to retain the supportable meaning of the Claim; and
- relationships among Quality, Harm, Risk, and Safety information where those matters are material to the Claim.

A material relationship shall not be removed, separated, rearranged, obscured, or communicated in a manner that materially changes the meaning supported by the applicable Findings.

Where Harm, Risk, or Safety information is material to the Claim, the relationships necessary to distinguish those concepts and their respective determinations shall be preserved. A Claim shall not collapse the sequence from a Quality condition to Harm, from Harm information to Risk, or from Risk to Safety in a manner that communicates a determination not supported by the applicable basis.

Where material Uncertainty exists at any stage of a relationship represented in the Claim, the Claim shall preserve that Uncertainty to the extent necessary to prevent a later statement or determination from communicating greater certainty than the underlying basis supports.

Preservation of Material Relationships does not require every relationship among all available Findings or supporting information to be communicated. The relationships required are those that are material to realization of the Claim's Intended Function under the applicable Quality Outcome Criteria.

A material relationship may be preserved directly within the Claim or, where appropriate, through a defined Interface to supporting information outside the Claim's Boundary, provided that the relationship remains sufficiently accessible and Traceable for the Claim's Intended Function.

Preservation of Material Relationships shall be distinguished from Substantive Support while remaining closely connected to it. Substantive Support concerns whether the substantive content of the Claim remains within what the applicable Findings can support. Preservation of Material Relationships concerns whether the relationships necessary to retain that supportable meaning remain intact.

A Claim may therefore contain individually supportable statements and still fail this Indicator where the treatment of their material relationships changes, weakens, obscures, or otherwise misrepresents what those statements collectively establish.

Preservation of Material Relationships shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.3 Material Sufficiency

Material Sufficiency is the Quality Factor concerning whether a Quality Claim communicates, or provides appropriate access to, the material information necessary for the Claim to realize its Intended Function.

Material Sufficiency shall be determined through one Quality Indicator:

- Material Information Sufficiency.

A Claim realizes Material Sufficiency where the information necessary for its recipient to understand and use the Claim for its intended purpose and within its applicable Context is communicated directly or made appropriately accessible through defined Interfaces.

Material Sufficiency does not require communication of all available Evidence, Findings, records, conditions, limitations, or supporting information.

The required information shall be determined by Materiality in relation to the Claim's Intended Function and relevant Intended Results, recipient, purpose, Context, Applicable Basis, applicable Quality Outcome Criteria, Critical Conditions, and Methodological Resolution.

Material information may include, as applicable:

- Findings necessary to understand what has been established about the original Quality Object;
- conditions or qualifications necessary to understand the scope or meaning of the Claim;
- material limitations and Uncertainty;
- information necessary to understand an applicable Conclusion or Refusal to Express a Conclusion;
- information concerning material Critical Conditions;
- information concerning Harm, Risk, or Safety where material to the Claim's Intended Function;
- information necessary to identify or use material Interfaces;
- information necessary to establish attribution where attribution is material to the Claim; and

- other information whose omission would materially impair the Claim's ability to realize its Intended Function.

Material Sufficiency concerns necessary information rather than information quantity.

A Claim may be extensive and remain materially insufficient where necessary information is omitted, inaccessible, obscured, or presented without information required for its intended use. Conversely, a concise Claim may realize Material Sufficiency where it communicates the necessary material information and provides appropriate access to supporting information where required.

Material information need not always be reproduced within the Claim's Boundary. It may be provided through a defined Interface where that arrangement is consistent with the Claim's Intended Function and applicable Quality Outcome Criteria and where the information remains sufficiently accessible and Traceable for its intended use.

Where material Harm, Risk, or Safety information is necessary for the Claim to realize its Intended Function, that information shall not be omitted merely because Harm, Risk, and Safety are methodologically distinct from Quality. Their distinctness shall be preserved while the information necessary for the Claim remains available.

Material Sufficiency shall be distinguished from Support.

Support concerns whether the substantive meaning communicated by the Claim remains within and preserves what the applicable Findings can support. Material Sufficiency concerns whether the information necessary for the Claim to perform its Intended Function is present or appropriately accessible.

A Claim may therefore satisfy Support while failing Material Sufficiency because necessary information is absent. Conversely, inclusion of extensive or materially sufficient information shall not establish Support where the substantive meaning communicated exceeds or alters what the applicable Findings can support.

Material Sufficiency shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.3.1 Material Information Sufficiency

Material Information Sufficiency is the Quality Indicator concerning whether the information necessary for a Quality Claim to realize its Intended Function is communicated directly or made appropriately accessible.

The Claim shall provide sufficient material information for its intended recipient to understand and use the Claim for its intended purpose and within its applicable Context.

Material Information Sufficiency shall be determined by the significance of information to realization of the Claim's Intended Function, rather than by the quantity of information communicated.

The determination shall consider, as applicable, whether the Claim provides or provides appropriate access to:

- the information necessary to understand what has been established about the Quality State of the original Quality Object;
- material conditions, qualifications, and limitations affecting the scope or meaning of the Claim;
- material Uncertainty;
- information necessary to understand an applicable Conclusion or Refusal to Express a Conclusion;
- information concerning applicable Critical Conditions where material to the Claim;
- material information concerning Harm, Risk, or Safety;
- information necessary to identify, access, and use material supporting information provided through an Interface;
- attribution or source information where necessary for the Claim's Intended Function or intended use; and

- other information whose absence would materially impair understanding, interpretation, or use of the Claim.

Information shall not be considered materially sufficient merely because it is technically available. Where information is necessary for realization of the Claim's Intended Function, its mode of communication or access shall be appropriate to the recipient, purpose, Context, and applicable Quality Outcome Criteria.

Material information maintained outside the Claim's Boundary may satisfy this Indicator where a defined Interface provides sufficiently reliable and usable access to that information and preserves the Traceability necessary for the Claim's intended use.

Where access to material information depends upon an Interface, material limitations, conditions, or loss of that Interface shall be considered in determining Material Information Sufficiency.

Material Harm, Risk, or Safety information shall not be omitted merely because those matters are analytically distinct from Quality. Where such information is necessary for the Claim to realize its Intended Function, it shall be communicated or made appropriately accessible while preserving the applicable distinctions among Quality, Harm, Risk, and Safety.

Material Uncertainty concerning Harm, Risk, or Safety shall remain available at the level to which it applies where omission of that Uncertainty could cause the Claim to communicate greater certainty than the applicable basis supports.

Material Information Sufficiency does not require inclusion of information that is not material to the Claim's Intended Function. Additional information shall not be treated as improving Claim Quality merely because more information has been provided.

Nor shall brevity, format, recipient preference, or practical convenience justify omission or inaccessibility of information that is material to realization of the Claim's Intended Function.

Material Information Sufficiency shall be distinguished from Intelligibility. This Indicator concerns whether the necessary material information is present or appropriately accessible. Intelligibility concerns whether the communicated information can be understood sufficiently for the Claim's intended use.

Material Information Sufficiency shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.4 Applicability

Applicability is the Quality Factor concerning whether a Quality Claim is suitable for the recipient, purpose, and Context for which the Claim is intended to function.

Applicability shall be determined through three Quality Indicators:

- Recipient Applicability;
- Purpose Applicability; and
- Context Applicability.

A Claim realizes Applicability where its supportable and materially sufficient content is suitable for its intended recipient, serves the purpose for which the Claim is made, and remains appropriate within the Context in which it is intended to function.

Applicability does not determine what is true about the original Quality Object or what the applicable Evidence-Supported Findings can support.

The recipient, purpose, or Context shall not create Findings, increase supported certainty, remove material limitations or Uncertainty, or justify a Claim that exceeds or alters the determined basis.

They may, however, affect:

- what information is material to the Claim;
- what information must be communicated directly or made accessible through an Interface;

- the level and form of explanation necessary;
- the terminology and level of detail appropriate to the Claim;
- the treatment of material conditions, limitations, and Uncertainty;
- the relevance and treatment of Harm, Risk, or Safety information;
- the applicable Quality Outcome Criteria; and
- the form in which the Claim must function for its intended use.

The three Applicability Indicators shall remain distinguishable.

Recipient Applicability concerns whether the Claim is suitable for the recipient for whom it is intended.

Purpose Applicability concerns whether the Claim is suitable for the purpose or use for which it is made.

Context Applicability concerns whether the Claim is suitable for the circumstances within which it is intended to function.

A Claim may realize one of these Indicators while failing another. Information may, for example, be suitable for a particular recipient but unsuitable for the decision for which it is being used, or suitable for both recipient and purpose while no longer applicable within a changed Context.

Applicability may therefore change without a change in the underlying Evidence-Supported Findings concerning the original Quality Object. A change in recipient, purpose, Context, time, Applicable Basis, material Interface, or another relevant condition may affect whether the Claim remains applicable for its intended function.

Where such a change is material, the continued Applicability of the Claim shall not be assumed solely because the Claim was applicable when originally made.

Where Harm, Risk, or Safety information is material to the Claim, Applicability shall consider whether that information and its associated conditions, limitations, criteria, and Uncertainty are suitable for the recipient, purpose, and Context in which the Claim is intended to function.

Applicability shall be distinguished from Communicative Realization. A Claim may contain information applicable to its recipient, purpose, and Context while failing to communicate that information intelligibly. Conversely, a Claim may be readily intelligible while communicating information that is not applicable to its intended recipient, purpose, or Context.

Applicability shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.4.1 Recipient Applicability

Recipient Applicability is the Quality Indicator concerning whether a Quality Claim is suitable for the recipient for whom the Claim is intended.

The Claim shall be capable of providing its intended recipient with the information necessary for the Claim to realize its Intended Function, at a level and in a form appropriate to that recipient under the applicable Quality Outcome Criteria.

Recipient Applicability shall consider, as applicable:

- the recipient's role in relation to the Claim;
- the information the recipient requires for the Claim's intended purpose;
- the level of detail necessary for the recipient's intended use;
- terminology, classifications, or other forms of expression required for that use;
- material conditions, qualifications, limitations, and Uncertainty that the recipient must be able to identify;
- material Harm, Risk, or Safety information relevant to the recipient's intended use;
- the recipient's need for access to supporting information through defined Interfaces; and
- other recipient-specific requirements established through the applicable Context Guide, Applicable Basis, or Quality Outcome Criteria.

Recipient Applicability does not permit the Claim to be changed merely to satisfy a recipient's preference where that change would exceed, distort, conceal, or otherwise alter what the applicable Evidence-Supported Findings can support.

The recipient's informational needs shall not create Findings, increase supported certainty, eliminate material Uncertainty, or justify omission of information that is material to realization of the Claim's Intended Function.

Where different recipients require different levels of detail, terminology, supporting information, or forms of communication, different expressions of a Claim may be appropriate, provided that each remains within the applicable Findings and preserves the material relationships necessary to retain their supportable meaning.

Recipient Applicability does not require all recipients to receive identical Claims. Differences in recipient role or informational need may justify differences in content or presentation where those differences are consistent with the specific Intended Function and applicable Quality Outcome Criteria.

Such differences shall not cause materially different substantive meanings to be communicated as though they were supported by the same Findings where the applicable basis does not support those differences.

Where material information is provided through an Interface rather than directly within the Claim, the Interface shall provide a form of access appropriate to the intended recipient and the Claim's Intended Function.

Where Harm, Risk, or Safety information is material to the recipient's intended use, the Claim shall communicate or provide appropriate access to that information while preserving the applicable distinctions, conditions, limitations, criteria, and Uncertainty.

Recipient Applicability shall be distinguished from Intelligibility. Recipient Applicability concerns whether the Claim is suitable for the particular recipient and that recipient's role and informational needs. Intelligibility concerns whether the information communicated by the Claim can be understood sufficiently for its intended use.

A Claim may therefore be intelligible in general while not being applicable to its intended recipient, or may contain information relevant to that recipient while failing to communicate it intelligibly.

Recipient Applicability shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.4.2 Purpose Applicability

Purpose Applicability is the Quality Indicator concerning whether a Quality Claim is suitable for the purpose for which the Claim is intended to be used.

The Claim shall provide a supportable and materially sufficient basis for the use identified by its specific Intended Function and applicable Quality Outcome Criteria.

Purpose Applicability shall consider, as applicable:

- the purpose for which the Claim is made;
- the type of use, action, determination, or decision the Claim is intended to support;
- the information necessary for that intended use;
- the level of detail and Methodological Resolution necessary for that use;
- material conditions, qualifications, limitations, and Uncertainty affecting that use;
- applicable Critical Conditions;
- material Harm, Risk, or Safety information relevant to the intended use;
- supporting information or records that must remain accessible through defined Interfaces; and
- other purpose-specific requirements established through the applicable Context Guide, Applicable Basis, or Quality Outcome Criteria.

A Claim shall not be considered applicable to a purpose merely because its subject matter is relevant to that purpose.

The Findings supporting the Claim, the Claim's content, and its applicable limitations shall provide a sufficient basis for the particular use for which the Claim is intended.

A Claim developed for one purpose shall not be presumed applicable to another purpose. Where the intended use changes, Purpose Applicability shall be reconsidered in relation to the new purpose and its applicable Quality Outcome Criteria.

A change in purpose may change what information is material, the required Methodological Resolution, applicable Critical Conditions, necessary Interfaces, or the treatment of material limitations and Uncertainty. Such a change shall not alter what the underlying Evidence-Supported Findings themselves establish.

Purpose Applicability shall not permit an intended use to expand the substantive support for the Claim. A purpose requiring a determination, degree of certainty, scope, or level of resolution beyond what the applicable Findings support shall not make the Claim applicable to that purpose.

Where the Claim is intended to support an action or decision involving Harm, Risk, or Safety, the information necessary for that purpose shall be communicated or made appropriately accessible. The distinctions among Quality, Harm, Risk, and Safety, together with material conditions, criteria, limitations, and Uncertainty, shall be preserved.

Purpose Applicability does not require a Claim to support every possible use to which its information could be put. It concerns the specific purpose or purposes included within the Claim's Intended Function.

Purpose Applicability shall be distinguished from Recipient Applicability. A Claim may be suitable for a particular recipient while not providing a sufficient basis for the purpose for which that recipient seeks to use it.

Purpose Applicability shall also be distinguished from Context Applicability. A Claim may be suitable for its intended purpose in one Context while changes in circumstances, time, Applicable Basis, Interfaces, or other material conditions make it unsuitable for the same purpose in another Context.

Purpose Applicability shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.4.3 Context Applicability

Context Applicability is the Quality Indicator concerning whether a Quality Claim is suitable for the circumstances within which the Claim is intended to function.

The Claim shall remain applicable to the relevant conditions, circumstances, time, setting, Applicable Basis, and other contextual elements material to realization of its Intended Function.

Context Applicability shall consider, as applicable:

- the circumstances in which the Claim is made and intended to be used;
- the time or period to which the Claim and its supporting Findings apply;
- the applicable physical, operational, organizational, social, regulatory, or other relevant setting;
- the Applicable Basis and Reference Layer relevant to the Claim;
- material assumptions, conditions, qualifications, and limitations;
- applicable Critical Conditions;
- material changes affecting the original Quality Object or the basis upon which the Claim was formed;
- the continued availability and relevance of material Interfaces and supporting information;
- material Harm, Risk, or Safety information and the conditions under which that information remains applicable; and
- other contextual requirements established through the applicable Context Guide, Applicable Basis, or Quality Outcome Criteria.

A Claim shall not be considered Context-applicable merely because it was applicable when originally made.

Where time, circumstances, Applicable Basis, material conditions, Interfaces, or other relevant contextual elements have changed, the continued applicability of the Claim shall be determined in relation to those changes.

A contextual change does not by itself establish that the Claim is no longer applicable. Its significance shall be determined according to whether the change materially affects the Claim's Intended Function, applicable Findings, material information, conditions of use, or applicable Quality Outcome Criteria.

Where a Claim concerns a Quality State established for a defined time or period, use of that Claim in a later Context shall preserve the temporal boundary of what was established. The Claim shall not communicate a past determination as establishing a present Quality State unless the applicable basis supports that use.

Similarly, a Claim formed under one Applicable Basis, set of conditions, or defined Boundary shall not be treated as applicable under a materially different basis, condition, or Boundary without determining whether the Claim remains suitable for the changed Context.

Context Applicability shall not permit changed circumstances to alter the meaning of the underlying Evidence-Supported Findings. Where a new Context requires Findings, Evidence, Methodological Resolution, or a determination not provided by the existing basis, the existing Claim shall not be treated as supplying that additional support.

Where Harm, Risk, or Safety information is material to the Claim, Context Applicability shall consider whether the conditions, assumptions, probability or severity basis, Safety criteria, limitations, and Uncertainty relevant to that information remain applicable in the current Context.

A Harm, Risk, or Safety determination applicable under one set of conditions shall not be presumed applicable where material conditions affecting that determination have changed.

Context Applicability shall be distinguished from Recipient Applicability and Purpose Applicability.

Recipient Applicability concerns suitability for the intended recipient. Purpose Applicability concerns suitability for the intended use. Context Applicability concerns suitability within the circumstances in which that recipient and purpose operate.

A Claim may therefore remain applicable to the same recipient and purpose while becoming Context-inapplicable because a material circumstance has changed.

Context Applicability shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.5 Communicative Realization

Communicative Realization is the Quality Factor concerning whether a Quality Claim communicates its content in a manner that permits the Claim to realize its Intended Function.

Communicative Realization shall be determined through one Quality Indicator:

- Intelligibility.

A Claim realizes Communicative Realization where its supportable, materially sufficient, and applicable content is communicated in a form that can be understood sufficiently for its intended use.

Communicative Realization concerns the realization of the Claim through communication. It does not determine whether the substantive content of the Claim is supported, whether all material information is present or appropriately accessible, or whether that information is applicable to the recipient, purpose, and Context. Those matters are addressed respectively through Support, Material Sufficiency, and Applicability.

Communicative Realization shall consider, as applicable:

- the clarity of the Claim's substantive statements;

- the organization and presentation of material information;
- the terminology, classifications, symbols, units, or other forms of expression used;
- the communication of material conditions, qualifications, limitations, and Uncertainty;
- the communication of an applicable Conclusion or Refusal to Express a Conclusion;
- the identification and communication of material Critical Conditions;
- the communication of material Harm, Risk, or Safety information;
- the intelligibility of references to supporting information provided through Interfaces; and
- other communication requirements established through the applicable Context Guide, Applicable Basis, or Quality Outcome Criteria.

Communicative Realization does not require a single form, format, vocabulary, level of technical detail, or mode of presentation for all Quality Claims.

The form of communication may vary according to the recipient, purpose, Context, specific Intended Function, applicable Quality Outcome Criteria, and the nature of the information being communicated.

Such variation shall not change the substantive meaning supported by the applicable Findings, remove material information, or obscure material relationships, conditions, limitations, or Uncertainty.

A Claim shall not be considered to realize Communicative Realization merely because its individual words or statements can be read or interpreted separately. The communication shall permit the material meaning of the Claim, including necessary qualifications and relationships, to be understood sufficiently for its intended use.

Additional complexity, technical detail, or volume of information shall not be presumed to improve Communicative Realization. Where such features unnecessarily impair understanding of material information, they may constrain realization of this Factor.

Similarly, simplification shall not be treated as improving Communicative Realization where it removes or obscures material meaning, qualifications, limitations, Uncertainty, or relationships necessary for the Claim to remain supportable and materially sufficient.

Where material information is provided through an Interface, the Claim shall communicate the existence, relevance, and means of using that Interface with sufficient intelligibility for the intended use.

Where Harm, Risk, or Safety information is material, its communication shall preserve the distinctions among Quality, Harm, Risk, and Safety and shall not obscure the conditions, criteria, limitations, or Uncertainty necessary to understand what has and has not been established.

Communicative Realization shall be distinguished from Applicability. Applicability concerns whether the Claim is suitable for its recipient, purpose, and Context. Communicative Realization concerns whether the applicable content is communicated so that it can be understood sufficiently for its intended use.

Communicative Realization shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

4.5.1 Intelligibility

Intelligibility is the Quality Indicator concerning whether the content of a Quality Claim can be understood sufficiently for the Claim to realize its Intended Function.

The Claim shall communicate its material content in a manner that permits the intended recipient to understand what the Claim communicates, what it does not establish, and the material conditions under which it is intended to be understood and used.

Intelligibility shall consider, as applicable:

- the clarity of substantive statements;
- the organization and presentation of material information;

- the clarity and consistency of terminology, classifications, symbols, units, and other forms of expression;
- the distinguishability of Findings, interpretations, conditions, qualifications, and other materially different forms of information;
- the communication of material limitations and Uncertainty;
- the clarity of an applicable Conclusion or Refusal to Express a Conclusion;
- the identification and communication of applicable Critical Conditions;
- the intelligibility of material relationships necessary to understand the Claim's supportable meaning;
- the communication of material Harm, Risk, or Safety information and the distinctions among those concepts;
- the identification and intelligibility of material Interfaces to supporting information; and
- other requirements affecting understanding established through the applicable Context Guide, Applicable Basis, or Quality Outcome Criteria.

Intelligibility does not require that a Claim be simplified to the greatest possible extent. The necessary level of technical detail, terminology, qualification, and methodological information shall be determined in relation to the Claim's Intended Function, recipient, purpose, Context, and applicable Quality Outcome Criteria.

Technical complexity shall not by itself establish lack of Intelligibility where that complexity is necessary for the intended use and is communicated at a level appropriate to the intended recipient.

Conversely, simplification shall not establish Intelligibility where it removes, obscures, or changes material information or relationships necessary to understand what has been established.

A Claim shall communicate material distinctions with sufficient clarity to prevent materially different matters from being understood as equivalent.

Where the Claim communicates a Conclusion concerning the original Quality Object, the distinction among a Positive Conclusion, Conditionally Positive Conclusion, and Negative Conclusion shall remain intelligible. Refusal to Express a Conclusion shall remain distinguishable from each substantive Conclusion and shall not be communicated as though it were a favorable or unfavorable determination of the Quality State of the original Quality Object.

Where a Conditionally Positive Conclusion is communicated, the material future condition or conditions upon which the Positive Conclusion depends shall be identifiable and understandable. The communication shall not imply that those conditions have already been fulfilled or that their future fulfillment has been established.

Where material Uncertainty exists, its communication shall permit the recipient to understand, to the extent required for the Claim's Intended Function, what is uncertain and how that Uncertainty limits or conditions what the Claim establishes.

Where Harm, Risk, or Safety information is material, the communication shall permit the applicable distinctions and relationships to be understood. In particular, the Claim shall not communicate a Quality condition, Harm-capable condition, Possible Harm, Risk determination, or Safety determination in a manner that makes one materially indistinguishable from another.

Where material supporting information is provided through an Interface, the Claim shall identify or communicate that Interface sufficiently for the intended recipient to understand its relevance and how the supporting information may be accessed or used as required by the applicable Quality Outcome Criteria.

Intelligibility does not require all supporting information to appear within the Claim's Boundary. Nor does it require every recipient to interpret the Claim identically. It requires communication sufficient for the intended recipient to understand the material meaning necessary for the Claim's intended use.

Intelligibility shall be distinguished from Material Information Sufficiency. Material Information Sufficiency concerns whether necessary material information is present or appropriately accessible.

Intelligibility concerns whether that information is communicated in a manner that permits its material meaning to be understood.

Intelligibility shall also be distinguished from Recipient Applicability. Recipient Applicability concerns whether the Claim is suitable for the intended recipient. Intelligibility concerns whether the Claim's communicated content can be understood sufficiently for its intended use.

A Claim may therefore contain all necessary material information and be applicable to its recipient, purpose, and Context while failing Intelligibility because its material meaning cannot be understood sufficiently for the intended use.

Intelligibility shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

5. Quality Determination

5.1 Determination of Claim Quality

The Quality of a Quality Claim shall be determined through an Evidence-based Quality Determination concerning the Claim as a defined Quality Object.

This determination is distinct from the Quality Determination concerning the original Quality Object.

The determination concerning the original Quality Object establishes Evidence-Supported Findings about the Quality State of that object. Those Findings may provide the substantive basis from which a Quality Claim is formed.

The determination of Claim Quality addresses a different question: what can be established about the Quality State of the Claim itself in relation to realization of the Claim's Intended Function and relevant Intended Results.

Determination of Claim Quality shall apply the four Quality Factors and seven Quality Indicators established by this Core:

- Support: Substantive Support; and Preservation of Material Relationships;
- Material Sufficiency: Material Information Sufficiency;
- Applicability: Recipient Applicability; Purpose Applicability; and Context Applicability; and
- Communicative Realization: Intelligibility.

The Quality Factors and Quality Indicators establish the invariant dimensions and determination functions through which Claim Quality is examined. They do not by themselves establish whether the applicable condition of a particular Claim realizes its Intended Function.

For each applicable Quality Indicator, the actual condition of the Claim shall be examined in relation to applicable Quality Outcome Criteria.

Applicable Quality Outcome Criteria establish the criteria against which Evidence concerning the Claim is evaluated and Evidence-Supported Findings concerning realization of the applicable Quality Indicator are established.

Applicable Quality Outcome Criteria may be established by this Core, by an applicable Context Guide, or through another justified application-specific basis consistent with the Applicable Basis and Reference Layer.

The determination pathway is therefore:

Quality Claim as Quality Object

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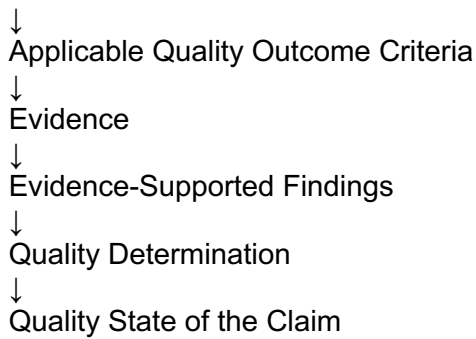
Intended Function and relevant Intended Results

↓

Quality Factors

↓

Quality Indicators



The determination shall be made in relation to the defined Claim, its Intended Function and relevant Intended Results, Boundary and Interfaces, recipient, purpose, Context, Applicable Basis, applicable Quality Outcome Criteria, and applicable Critical Conditions.

Evidence used to determine Claim Quality may include, as applicable:

- the Claim itself;
- the applicable Evidence-Supported Findings concerning the original Quality Object;
- the Synthesis of Material Findings supporting the original Conclusion or Refusal to Express a Conclusion;
- information concerning the relationship between the original Findings and the content of the Claim;
- material supporting information and records;
- information concerning the operation and limitations of material Interfaces;
- information concerning the intended recipient, purpose, and Context;
- the Applicable Basis, Reference Layer, and applicable Quality Outcome Criteria;
- information concerning material conditions, limitations, and Uncertainty;
- material Harm, Risk, or Safety information; and
- other Evidence necessary to establish Findings concerning realization of the Claim's Quality Factors and Quality Indicators.

Use of Findings or supporting information from the determination concerning the original Quality Object does not convert the determination of Claim Quality into a redetermination of the original Quality Object.

The original Findings remain Findings concerning the original Quality Object. In determining Claim Quality, they may serve as part of the basis for examining whether the Claim remains substantively supported, preserves material relationships, contains or provides access to necessary material information, is applicable to its recipient, purpose, and Context, and is communicated intelligibly.

Evidence shall not be treated as a Finding merely because it is available to the determination.

Evidence shall be evaluated in relation to the applicable Quality Outcome Criteria, and the scope and certainty of a resulting Finding shall not exceed what the Evidence and its Evidence Quality support.

Evidence Quality, Materiality, Uncertainty, Traceability, and applicable Critical Conditions shall be considered according to their respective functions in determining what Findings concerning Claim Quality can be established.

Where Harm, Risk, or Safety information is material to the Claim, the determination shall examine the Claim's treatment of that information through the applicable Claim Quality Factors, Quality Indicators, and Quality Outcome Criteria while preserving the methodological distinctions among Quality, Harm, Risk, and Safety.

Determination of Claim Quality shall not presume that a Claim is of favorable Quality because the Claim reports a favorable Quality State of the original Quality Object.

Similarly, a Claim reporting an unfavorable Quality State, a material deficiency, Possible Harm, Risk, or another adverse matter concerning the original Quality Object may itself realize favorable Claim Quality where it realizes its own Intended Function under the applicable Quality Outcome Criteria.

The Quality State of the Claim and the Quality State of the original Quality Object shall therefore remain distinct.

Findings established through determination of Claim Quality shall concern the Claim as the Quality Object under determination. Those Findings provide the basis for subsequent consideration of interaction among Factors and Indicators, Synthesis of Material Findings, and the applicable Conclusion or Refusal to Express a Conclusion concerning the Quality of the Claim.

Determination of Claim Quality shall remain bounded by the available Evidence, Evidence Quality, applicable Quality Outcome Criteria, Methodological Resolution, and material Uncertainty. Where the available basis does not support a Finding or Conclusion, the determination shall not supply one by inference beyond what that basis supports.

5.2 Evidence-Supported Findings

Determination of the Quality of a Quality Claim shall be based on Evidence-Supported Findings concerning the Claim as the Quality Object under determination.

For each applicable Quality Indicator, the determination shall examine Evidence in relation to the applicable Quality Outcome Criteria and establish what Finding, if any, that Evidence supports concerning realization of the Indicator.

The basic determination relationship is:

Quality Indicator



Applicable Quality Outcome Criteria



Evidence



Evidence-Supported Finding

Applicable Quality Outcome Criteria may be established by this Core, by an applicable Context Guide, or through another justified application-specific basis consistent with the Applicable Basis and Reference Layer.

Where this Core establishes an applicable Quality Outcome Criterion, that criterion shall apply unless a more specific applicable provision permissibly supplements it without changing the determination function of the applicable Core Quality Factor or Quality Indicator.

Where the realization of an Indicator depends upon the particular class, purpose, recipient, Context, or other application-specific condition of a Claim, the applicable Quality Outcome Criteria may be established or further specified through a Context Guide or another justified application-specific basis.

The source and applicability of the Quality Outcome Criteria used in the determination shall remain Traceable.

An Evidence-Supported Finding concerning Claim Quality shall state only what the available Evidence, considered in relation to the applicable Quality Outcome Criteria, can support about the actual condition of the Claim.

A Finding may establish, as applicable:

- realization of an applicable Quality Outcome Criterion;
- non-realization of an applicable Quality Outcome Criterion;
- realization subject to an identified condition or limitation;
- a condition relevant to more than one Quality Factor or Quality Indicator;
- a material limitation or Uncertainty affecting what can be established; or
- that the available Evidence does not support determination of the condition being examined.

A Finding shall not extend beyond the scope, certainty, conditions, or Methodological Resolution supported by the Evidence.

Where the Evidence supports only part of the condition addressed by an applicable Quality Outcome Criterion, the Finding shall remain bounded to that part.

Where material Evidence is insufficient, unavailable, unreliable for the intended use, inapplicable, or otherwise unable to support the required Finding, the absence of a supportable Finding shall not be converted into a favorable or unfavorable Finding about the Quality of the Claim.

Evidence-Supported Findings concerning Claim Quality shall remain distinct from the Evidence-Supported Findings concerning the original Quality Object.

Findings concerning the original Quality Object may provide Evidence or other relevant basis for determining whether the Claim realizes Support, Material Sufficiency, Applicability, or Communicative Realization. They do not thereby become Findings concerning the Quality State of the Claim.

Similarly, a Finding concerning Claim Quality shall not alter, replace, or redetermine a Finding concerning the original Quality Object.

Where Harm, Risk, or Safety information is material to the Claim, Findings concerning the Claim's treatment of that information shall be established through the applicable Claim Quality Indicators and Quality Outcome Criteria.

Such Findings concern the Quality of the Claim's communication, support, material sufficiency, applicability, or intelligibility. They shall not be treated as new Harm, Risk, or Safety determinations unless those determinations are separately established through their applicable basis.

Material limitations, conditions, Critical Conditions, and Uncertainty affecting a Finding shall remain associated with that Finding to the extent necessary for subsequent Synthesis and Conclusion.

Each material Finding shall remain Traceable, as applicable, to:

- the Quality Indicator being examined;
- the applicable Quality Outcome Criterion;
- the Evidence supporting the Finding;
- relevant Evidence Quality considerations;
- material conditions, limitations, and Uncertainty; and
- the Applicable Basis and Reference Layer supporting the determination.

Evidence-Supported Findings established through the applicable Quality Indicators and Quality Outcome Criteria provide the basis for considering interaction among the Claim Quality Factors and Indicators and for the subsequent Synthesis of Material Findings.

5.3 Interaction Among Factors and Indicators

The Quality of a Quality Claim shall be determined through consideration of the applicable Quality Factors and Quality Indicators together, while preserving their distinct determination functions.

The four Quality Factors established by this Core — Support, Material Sufficiency, Applicability, and Communicative Realization — examine different dimensions of the Claim's realization of its Intended Function.

The seven Quality Indicators provide the more specific basis for examining those dimensions through applicable Quality Outcome Criteria.

A condition identified through one Quality Factor or Quality Indicator may affect the significance, interpretation, or realization of another Factor or Indicator.

Such interaction shall be considered where it is material to the Quality Determination.

For example:

- a limitation in Substantive Support may constrain what information can responsibly be communicated for Material Information Sufficiency;
- failure to preserve a material relationship may affect both Support and the intelligibility of the resulting communication;

- omission of material information may affect Material Information Sufficiency and may also affect Recipient, Purpose, or Context Applicability;
- a change in Context may affect Context Applicability and may change what information is material to the Claim;
- limitations in Recipient or Purpose Applicability may affect the level, form, or organization of communication necessary for Intelligibility;
- failure to communicate a material condition, limitation, or Uncertainty intelligibly may affect the recipient's ability to understand the substantive meaning and permissible use of the Claim; and
- the treatment of material Harm, Risk, or Safety information may affect more than one Factor or Indicator where its support, inclusion, applicability, relationships, or communication are material to the Claim's Intended Function.

Interaction does not make the Factors or Indicators interchangeable.

A condition affecting more than one Factor or Indicator shall be examined through each applicable determination function and the applicable Quality Outcome Criteria.

The same Evidence may support Findings concerning more than one Quality Indicator where it is applicable to each determination. Use of the same Evidence does not merge the resulting Findings or the Indicators to which they relate.

Similarly, one Evidence-Supported Finding may be material to the determination of another Factor or Indicator without losing its identity or its Traceability to the Quality Outcome Criterion through which it was established.

Where interaction among Factors or Indicators materially affects the determination, that interaction shall remain visible in the applicable Findings and subsequent Synthesis of Material Findings.

Interaction shall not be used to infer realization of one Factor or Indicator solely from realization of another.

For example, a Claim that is intelligible is not thereby substantively supported. A Claim that is substantively supported is not thereby materially sufficient. A Claim containing materially sufficient information is not thereby applicable to its intended purpose or Context. A Claim applicable to its recipient, purpose, and Context is not thereby intelligible.

Conversely, a limitation identified through one Factor or Indicator shall not automatically establish non-realization of another. Its effect on another Factor or Indicator shall be determined through the applicable Quality Outcome Criteria and Evidence.

Where a material condition affects several Factors or Indicators, its significance shall be considered without unnecessary duplication of the underlying Evidence or Finding. The relationships among the affected Findings shall remain Traceable.

Material Uncertainty affecting an interaction among Factors or Indicators shall remain visible and shall not be resolved merely by strength identified elsewhere in the Claim Quality structure.

Applicable Critical Conditions shall also be considered where their realization, non-realization, or unresolved status affects one or more Factors or Indicators.

The interaction among Factors and Indicators shall therefore be considered as part of the overall Quality Determination while preserving the identity, determination function, applicable Quality Outcome Criteria, Findings, limitations, and Uncertainty associated with each material part of the determination.

5.4 Non-Substitutability and Non-Compensability

The Quality Factors and Quality Indicators established by this Core perform distinct functions in determining the Quality of a Quality Claim.

One Quality Factor or Quality Indicator shall not be used as a substitute for another where the other is applicable to the determination.

Similarly, realization of one Factor or Indicator shall not automatically compensate for non-realization, a material limitation, or an unresolved condition affecting another Factor or Indicator.

For example:

- strong Substantive Support does not compensate for omission of information necessary for Material Information Sufficiency;
- extensive material information does not compensate for substantive content that exceeds or alters what the applicable Findings support;
- suitability for a recipient does not compensate for a Claim that is unsuitable for its intended purpose or Context;
- applicability to a purpose does not compensate for a material change in Context that makes the Claim no longer applicable;
- Intelligibility does not compensate for lack of Support, Material Sufficiency, or Applicability; and
- technical detail, clarity, or persuasive presentation does not compensate for a Claim that communicates a substantive meaning not supported by the applicable Findings.

Non-Compensability does not mean that every limitation or non-realization has the same significance.

The significance of a condition shall be determined in relation to the applicable Quality Outcome Criteria, the Claim's Intended Function and relevant Intended Results, Materiality, recipient, purpose, Context, applicable Critical Conditions, and the Evidence-Supported Findings.

A limitation in one Factor or Indicator may have no material effect on the overall determination where the applicable Quality Outcome Criteria establish that the condition is not material to realization of the Claim's Intended Function.

Conversely, a condition affecting a single Factor or Indicator may materially constrain the overall Quality Determination where that condition is necessary for realization of the Claim's Intended Function or constitutes an applicable Critical Condition.

Where a condition affects more than one Factor or Indicator, its effect shall be examined through each applicable determination function without treating repeated consideration as independent compensating strengths or weaknesses.

The use of different Quality Outcome Criteria for different Indicators does not make the Indicators interchangeable. Each applicable criterion shall be evaluated in relation to the determination function of the Factor or Indicator to which it applies.

Where an applicable Quality Outcome Criterion is not realized, strength established through another criterion shall not be used to treat that criterion as realized unless the Applicable Basis expressly establishes a relationship that permits such treatment and that relationship is consistent with the determination functions established by this Core.

No numerical averaging, weighting, scoring, or balancing among Factors or Indicators shall be presumed by this Core.

Where an applicable Context Guide or other justified application-specific basis establishes a method involving weighting, aggregation, thresholds, or another form of combined evaluation, that method shall preserve the distinct determination functions of the Core Factors and Indicators and shall not conceal a material non-realization, limitation, Critical Condition, or Uncertainty.

Material Harm, Risk, or Safety information shall not be treated as compensated merely because other aspects of the Claim realize their applicable Quality Outcome Criteria.

Where treatment of Harm, Risk, or Safety information is material to Support, Material Sufficiency, Applicability, or Communicative Realization, any applicable limitation shall remain visible through the affected Factor or Indicator and shall be considered according to its material significance.

Material Uncertainty shall likewise not be eliminated or reduced merely because other Factors or Indicators are strongly supported.

Non-Substitutability and Non-Compensability therefore preserve the distinct informational value of the Findings established through the four Quality Factors and seven Quality Indicators while allowing their material interactions to be considered in the overall Quality Determination.

The resulting Findings, including material limitations, interactions, Critical Conditions, and Uncertainty, shall remain distinguishable and Traceable for the subsequent Synthesis of Material Findings.

5.5 Synthesis of Material Findings

Following establishment of the applicable Evidence-Supported Findings, the material Findings concerning the Quality of the Claim shall be considered through a Synthesis of Material Findings.

There shall be one Synthesis of Material Findings for the Quality Determination of the Claim.

The Synthesis shall determine what Conclusion, if any, the material Claim-quality Findings support concerning the Quality State of the Claim. This is separate from any overall Conclusion concerning the original Quality Object. If the Claim's Intended Function does not require such an original-object Conclusion, its absence shall not prevent synthesis or determination of the Quality of the Claim.

The Synthesis shall consider material Findings established through the four Quality Factors and seven Quality Indicators together while preserving the identity, determination function, applicable Quality Outcome Criteria, and evidentiary basis of those Findings.

The Synthesis shall consider, as applicable:

- Findings concerning realization or non-realization of applicable Quality Outcome Criteria;
- Findings concerning Support, including Substantive Support and Preservation of Material Relationships;
- Findings concerning Material Sufficiency, including Material Information Sufficiency;
- Findings concerning Applicability, including Recipient Applicability, Purpose Applicability, and Context Applicability;
- Findings concerning Communicative Realization, including Intelligibility;
- material interactions among Factors and Indicators;
- material conditions, qualifications, and limitations;
- applicable Critical Conditions and their status;
- material Uncertainty;
- material Harm, Risk, or Safety information insofar as its treatment affects the Quality of the Claim;
- the effects of Non-Substitutability and Non-Compensability; and
- other Findings or relationships material to determining realization of the Claim's Intended Function and relevant Intended Results.

Materiality shall govern which Findings and relationships require consideration in the Synthesis.

The Synthesis shall not be based merely on the number of favorable or unfavorable Findings.

Nor shall the Synthesis presume that realization of a majority of Quality Indicators establishes favorable Claim Quality, or that non-realization of a single Indicator necessarily establishes unfavorable Claim Quality.

The significance of each material Finding shall be considered in relation to the Claim's Intended Function and relevant Intended Results, applicable Quality Outcome Criteria, recipient, purpose, Context, Applicable Basis, and applicable Critical Conditions.

The Synthesis shall preserve Non-Substitutability and Non-Compensability. Strength established through one Factor, Indicator, or Quality Outcome Criterion shall not be used to erase a material limitation or non-realization established through another where that condition remains relevant to realization of the Claim's Intended Function.

Where a material condition affects more than one Factor or Indicator, the Synthesis shall consider the condition and its relationships without treating repeated expression of the same underlying condition as multiple independent Findings.

Where Findings point in different directions, their relationship and material significance shall be examined rather than resolved through simple averaging, counting, or balancing.

Where an applicable Critical Condition is not realized or remains unresolved, its effect on the permissible Conclusion, if any, shall be determined from the applicable Findings, Quality Outcome Criteria, and basis for that Critical Condition.

Non-realization or unresolved status of a Critical Condition shall not automatically establish a Negative Conclusion.

A Negative Conclusion requires affirmative support in the Findings for non-realization of the Claim's Intended Function or relevant Intended Results under the applicable Quality Outcome Criteria.

Where the Findings support realization subject to one or more identified material conditions to be fulfilled in the future, the Synthesis may support a Conditionally Positive Conclusion where the requirements for that Conclusion are satisfied.

The existence of a future condition shall not itself establish that the condition will be fulfilled.

Where insufficient Evidence, an Evidence Quality limitation, material Uncertainty, an unresolved condition, or another limitation prevents the Findings from supporting a Positive, Conditionally Positive, or Negative Conclusion, the Synthesis shall not convert that limitation into a substantive Conclusion.

In such circumstances, the Synthesis may support Refusal to Express a Conclusion.

A Claim may appropriately communicate particular Evidence-Supported Findings concerning the original Quality Object without expressing an overall Conclusion about that object. In that case, the Synthesis shall evaluate the Claim-quality Findings against the Claim's own Intended Function and applicable Quality Outcome Criteria. The absence of an original-object Conclusion shall not be treated as a deficiency unless that Conclusion is material to the Claim's Intended Function or is otherwise required by the Applicable Basis.

Where Harm, Risk, or Safety information is material to the Claim Quality Determination, the Synthesis shall preserve the distinctions among Quality, Harm, Risk, and Safety.

A Harm-capable condition, Possible Harm, Risk determination, or Safety determination shall not be substituted for a Finding concerning Claim Quality. Rather, the Claim's treatment of such information shall be considered through the applicable Claim Quality Factors, Indicators, and Quality Outcome Criteria.

Material Uncertainty concerning Harm, Risk, or Safety shall remain visible through the Synthesis to the level at which it affects the Claim Quality Determination.

The Synthesis shall not create new Evidence-Supported Findings. It shall consider the material Findings already established and their relevant relationships to determine what Conclusion, if any, those Findings support concerning the Quality State of the Claim.

The basis of the Synthesis shall remain Traceable to the material Findings, applicable Quality Outcome Criteria, Evidence, material conditions and limitations, Critical Conditions, and Uncertainty upon which it depends.

The resulting Synthesis provides the basis for the applicable Conclusion concerning the Quality State of the Claim or, where no substantive Conclusion is supportable, Refusal to Express a Conclusion.

5.6 Conclusion or Refusal to Express a Conclusion

After the Synthesis of Material Findings, the Claim-quality determination shall establish what Conclusion, if any, those Findings support concerning the Quality State of the Claim.

In this Section, the Quality Object under determination is the Quality Claim itself, not the original Quality Object about which the Claim communicates.

The Conclusion concerning the Quality State of the Claim shall be distinguished from any Conclusion or Refusal to Express a Conclusion concerning the original Quality Object about which the Claim communicates.

These are separate matters concerning separate Quality Objects.

A Quality Claim is not required to express a Positive, Conditionally Positive, or Negative Conclusion, or a Refusal to Express a Conclusion, concerning the original Quality Object unless expression of such a Conclusion or Refusal is necessary for realization of the Claim's Intended Function or is otherwise required by the Applicable Basis.

The Intended Function of a particular Quality Claim may instead require communication of one or more applicable Evidence-Supported Findings concerning the original Quality Object without requiring an overall Conclusion concerning that object's Quality State.

Where this is the case, the Claim may be limited to those Findings and other material information necessary for realization of its Intended Function.

Omission of an overall Conclusion or Refusal concerning the original Quality Object shall not constitute non-realization of Claim Quality where such a Conclusion or Refusal is not material to realization of the Claim's Intended Function and is not otherwise required by the Applicable Basis.

The Claim shall not introduce an overall Conclusion concerning the original Quality Object merely because the recipient requests particular information where the applicable Findings do not support, or the Claim's Intended Function does not require, such a Conclusion.

Where a Conclusion or Refusal concerning the original Quality Object is included in the Claim, its treatment shall be examined through the applicable Claim Quality Factors, Quality Indicators, and Quality Outcome Criteria.

In particular, the determination shall examine whether that Conclusion or Refusal remains substantively supported, preserves material relationships, is accompanied by necessary material information, is applicable to the recipient, purpose, and Context, and is communicated with sufficient Intelligibility.

The presence or absence of a Conclusion concerning the original Quality Object does not determine whether a Conclusion can be reached concerning the Quality State of the Claim itself.

A Claim that appropriately communicates specific Findings without an overall Conclusion concerning the original Quality Object may realize its Intended Function and support a Positive Conclusion concerning the Quality State of the Claim.

Conversely, inclusion of a Positive, Conditionally Positive, or Negative Conclusion concerning the original Quality Object does not establish favorable Quality of the Claim.

Following Synthesis of the material Findings concerning the Claim itself, the permissible substantive Conclusions concerning the Quality State of the Claim are:

- Positive Conclusion;
- Conditionally Positive Conclusion; and
- Negative Conclusion.

Where the available basis does not support any of these substantive Conclusions concerning the Quality State of the Claim, the determination shall result in Refusal to Express a Conclusion.

Refusal to Express a Conclusion is not a substantive Conclusion and shall not be interpreted as either a favorable or unfavorable determination of the Quality State of the Claim.

A Positive Conclusion concerning the Quality State of the Claim shall require affirmative support that the Claim realizes its Intended Function and relevant Intended Results as required within the applicable scope and conditions and under the applicable Quality Outcome Criteria.

A Conditionally Positive Conclusion concerning the Quality State of the Claim shall require affirmative support for a Positive Conclusion subject to one or more identified material conditions to be fulfilled in the future.

A Negative Conclusion concerning the Quality State of the Claim shall require affirmative support in the material Findings and their Synthesis that the Claim does not realize its Intended Function or

relevant Intended Results as required within the applicable scope and conditions and under the applicable Quality Outcome Criteria.

Failure to support a Positive Conclusion concerning the Claim shall not by itself support a Negative Conclusion.

Insufficient Evidence, an Evidence Quality limitation, an Evidence gap, material Uncertainty, or an unresolved condition shall not by itself constitute affirmative support for a Negative Conclusion.

Where such limitations prevent the Synthesis from supporting a Positive, Conditionally Positive, or Negative Conclusion concerning the Quality State of the Claim, Refusal to Express a Conclusion shall be used.

The status of an applicable Critical Condition shall be considered in determining the permissible Conclusion concerning the Claim.

Non-realization or unresolved status of a Critical Condition does not automatically establish a Negative Conclusion. Its effect shall depend on what the applicable Findings establish concerning realization of the Claim's Intended Function and relevant Intended Results.

An unresolved Critical Condition does not automatically exclude a Conditionally Positive Conclusion. Where the Findings support realization subject to future fulfillment of an identified material condition, a Conditionally Positive Conclusion may be appropriate where the applicable requirements for that Conclusion are satisfied.

Uncertainty alone shall not be used to convert an otherwise unsupported determination into a Conditionally Positive Conclusion.

The favorable or unfavorable Quality State of the original Quality Object shall not determine the Conclusion concerning the Quality State of the Claim.

A Claim communicating unfavorable Findings, a Negative Conclusion, or a Refusal concerning the original Quality Object may itself realize its Intended Function and support a Positive Conclusion concerning the Quality State of the Claim.

Similarly, a Claim communicating favorable Findings or a Positive Conclusion concerning the original Quality Object may fail to realize its own Intended Function.

Where Harm, Risk, or Safety information is material to the Claim, the Conclusion concerning the Quality State of the Claim shall concern the Claim's realization of its Intended Function in treating that information through the applicable Factors, Indicators, and Quality Outcome Criteria.

Such a Conclusion shall not itself constitute a Harm, Risk, or Safety determination unless that separate determination has been established through its applicable basis.

The basis for the Conclusion or Refusal concerning the Quality State of the Claim shall remain Traceable to the Synthesis of Material Findings, the material Evidence-Supported Findings, applicable Quality Outcome Criteria, Evidence, material conditions and limitations, Critical Conditions, and Uncertainty.

The specific requirements governing each permissible Conclusion or Refusal concerning the Quality State of the Claim are established in Sections 5.6.1 through 5.6.4.

5.6.1 Positive Conclusion

A Positive Conclusion concerning the Quality State of the Quality Claim shall be expressed only where the Synthesis of Material Findings supports that the Claim realizes its Intended Function and relevant Intended Results as required within the applicable scope and conditions.

For purposes of this determination, the Quality Claim is the defined Quality Object.

A Positive Conclusion shall be based on affirmative Evidence-Supported Findings established through the applicable Quality Factors, Quality Indicators, and Quality Outcome Criteria and their Synthesis.

The determination shall establish, to the extent required for realization of the Claim's Intended Function, that:

- the substantive content of the Claim remains within what the applicable Findings concerning the original Quality Object support;
- material relationships necessary to preserve the supportable meaning of the Claim are preserved;
- information material to realization of the Claim's Intended Function is communicated or appropriately accessible through defined Interfaces;
- the Claim is applicable to its intended recipient;
- the Claim is applicable to its intended purpose;
- the Claim is applicable within the relevant Context; and
- the material meaning of the Claim is communicated with sufficient Intelligibility for its intended use.

These matters shall be determined through the applicable Quality Outcome Criteria.

A Positive Conclusion shall not be based merely on the presence of the applicable Quality Factors and Quality Indicators, the number of favorable Findings, or a general impression that the Claim is adequate.

A Positive Conclusion does not require perfection, maximum information, maximum detail, or the absence of every unfavorable Finding concerning the Claim.

An unfavorable Finding does not necessarily prevent a Positive Conclusion where the Synthesis establishes that the Finding does not materially prevent realization of the Claim's Intended Function or relevant Intended Results under the applicable Quality Outcome Criteria.

A Positive Conclusion shall not disregard a material non-realization, an applicable Critical Condition, or a Non-Compensable condition that prevents responsible support for the Positive Conclusion.

Favorable realization established through one Quality Factor, Quality Indicator, or Quality Outcome Criterion shall not be used to compensate for such a condition elsewhere in the determination.

Where material Uncertainty exists, a Positive Conclusion may be expressed only where that Uncertainty does not prevent affirmative support for realization of the Claim's Intended Function and relevant Intended Results within the applicable scope and conditions.

The scope and certainty of the Positive Conclusion shall not exceed what the applicable Findings and their Synthesis support.

A Positive Conclusion concerning the Quality State of the Claim does not require the Claim itself to express a Positive, Conditionally Positive, or Negative Conclusion, or a Refusal to Express a Conclusion, concerning the original Quality Object.

Where the Claim's Intended Function is appropriately realized through communication of particular Evidence-Supported Findings concerning the original Quality Object, and an overall Conclusion concerning that object is neither material nor otherwise required by the Applicable Basis, absence of such an overall Conclusion shall not prevent a Positive Conclusion concerning the Quality State of the Claim.

Where the Claim does express a Conclusion or Refusal concerning the original Quality Object, that communication shall satisfy the applicable Claim Quality requirements and Quality Outcome Criteria.

A Positive Conclusion concerning the Quality State of the Claim does not establish that the Quality State of the original Quality Object is favorable.

A Claim communicating unfavorable Findings, a Negative Conclusion, or a Refusal to Express a Conclusion concerning the original Quality Object may itself support a Positive Conclusion concerning its own Quality State where the Claim realizes its Intended Function and relevant Intended Results as required.

Conversely, favorable Findings or a Positive Conclusion concerning the original Quality Object do not establish a Positive Conclusion concerning the Quality State of the Claim.

Where a material condition must be fulfilled in the future before the Findings can support realization of the Claim's Intended Function and relevant Intended Results as required, the requirements for a Conditionally Positive Conclusion shall be considered.

Where the available basis does not affirmatively support realization, the absence of support for a Positive Conclusion shall not be converted into a Negative Conclusion.

Where Harm, Risk, or Safety information is material to the Claim, a Positive Conclusion concerning the Quality State of the Claim requires that the Claim's treatment of that information realize the applicable Claim Quality requirements and Quality Outcome Criteria.

A Positive Conclusion concerning the Quality State of the Claim does not itself establish absence of Harm or Risk or establish Safety concerning the original Quality Object or any other subject.

The basis for a Positive Conclusion concerning the Quality State of the Claim shall remain Traceable to the Synthesis of Material Findings and to the applicable Findings, Quality Outcome Criteria, Evidence, material conditions and limitations, Critical Conditions, and Uncertainty upon which the Conclusion depends.

5.6.2 Conditionally Positive Conclusion

A Conditionally Positive Conclusion concerning the Quality State of the Quality Claim shall be expressed only where the Synthesis of Material Findings supports a Positive Conclusion subject to one or more identified material conditions to be fulfilled in the future.

For purposes of this determination, the Quality Claim is the defined Quality Object.

The material Findings shall provide affirmative support for realization of the Claim's Intended Function and relevant Intended Results subject to the identified future condition or conditions.

A Conditionally Positive Conclusion shall identify, to the extent necessary for its meaning and use:

- the material future condition or conditions upon which the Positive Conclusion depends;
- the aspect of the Claim's Intended Function or relevant Intended Results affected by those conditions;
- the applicable Quality Factor, Quality Indicator, and Quality Outcome Criterion to which the condition relates, where material;
- what must occur for a Positive Conclusion to become supportable without the condition;
- material limitations and Uncertainty concerning the condition; and
- any applicable Critical Condition or Non-Compensable condition affecting the permissible Conclusion.

The identified future condition shall have a supportable relationship to the basis for the Conditionally Positive Conclusion.

The condition shall not be stated merely as a general expectation, aspiration, recommendation, possibility of improvement, or unspecified future action.

A Conditionally Positive Conclusion does not establish that the identified future condition will be fulfilled.

Evidence that a future action is planned, required, authorized, financed, scheduled, feasible, or expected shall not by itself establish that the condition has been fulfilled or will be fulfilled.

The distinction between the current Quality State of the Claim and the future condition upon which the Positive Conclusion depends shall remain clear.

A Conditionally Positive Conclusion shall not be used merely because a Positive Conclusion cannot presently be supported.

Insufficient Evidence, an Evidence gap, an Evidence Quality limitation, material Uncertainty, or an unresolved matter shall not by itself provide a basis for a Conditionally Positive Conclusion.

Where such a limitation prevents establishment of the affirmative Findings necessary to support realization of the Claim's Intended Function, the determination shall consider whether Refusal to Express a Conclusion is required.

Similarly, a Conditionally Positive Conclusion shall not be used where the material Findings affirmatively support a Negative Conclusion concerning the current Quality State of the Claim merely because corrective action, additional information, revised communication, or another future change may be possible.

An unresolved Critical Condition does not automatically exclude a Conditionally Positive Conclusion.

Where the Findings affirmatively support realization subject to future fulfillment of an identified material Critical Condition, a Conditionally Positive Conclusion may be expressed where the applicable Quality Outcome Criteria and Applicable Basis permit that Conclusion.

Where the status of the Critical Condition is itself insufficiently established, that lack of support shall not be converted into an assumption that the condition will be fulfilled.

A Conditionally Positive Conclusion concerning the Quality State of the Claim does not require the Claim itself to express a Conditionally Positive Conclusion, or any other overall Conclusion, concerning the original Quality Object.

The condition supporting a Conditionally Positive Conclusion about the Claim shall concern realization of the Claim's own Intended Function and relevant Intended Results.

For example, the condition may concern future completion, correction, provision, verification, accessibility, applicability, or communication of something material to realization of the Claim's Intended Function.

Such a condition shall not be confused with a future condition concerning the original Quality Object merely because the Claim communicates information about that object.

Where the Claim itself communicates a Conditionally Positive Conclusion concerning the original Quality Object, the future conditions associated with that original-object Conclusion shall remain distinguishable from any future condition supporting a Conditionally Positive Conclusion concerning the Quality State of the Claim.

Where Harm, Risk, or Safety information is material, a Conditionally Positive Conclusion concerning the Claim shall preserve the applicable distinctions among Quality, Harm, Risk, and Safety and shall identify any material future condition affecting the Claim's treatment of that information.

A future reduction of Harm or Risk, or future establishment of Safety, shall not be presumed merely because a Conditionally Positive Conclusion concerning Claim Quality is expressed.

The scope and certainty of the Conditionally Positive Conclusion shall not exceed what the applicable Findings and their Synthesis support.

The basis for the Conditionally Positive Conclusion, including the identified future conditions, shall remain Traceable to the applicable Synthesis of Material Findings, Evidence-Supported Findings, Quality Outcome Criteria, Evidence, Critical Conditions, limitations, and Uncertainty.

5.6.3 Negative Conclusion

A Negative Conclusion concerning the Quality State of the Quality Claim shall be expressed only where the Synthesis of Material Findings affirmatively supports that the Claim does not realize its Intended Function or relevant Intended Results as required within the applicable scope and conditions.

For purposes of this determination, the Quality Claim is the defined Quality Object.

A Negative Conclusion shall be based on affirmative Evidence-Supported Findings established through the applicable Quality Factors, Quality Indicators, and Quality Outcome Criteria and their Synthesis.

The affirmative basis for a Negative Conclusion may include, as applicable, material non-realization concerning:

- Substantive Support;
- Preservation of Material Relationships;
- Material Information Sufficiency;
- Recipient Applicability;
- Purpose Applicability;
- Context Applicability;
- Intelligibility;
- an applicable Critical Condition;
- a Non-Compensable condition; or
- another material condition established through the applicable Quality Outcome Criteria that prevents realization of the Claim's Intended Function or relevant Intended Results as required.

Non-realization of an individual Quality Outcome Criterion, Quality Indicator, or Quality Factor shall not automatically require a Negative Conclusion.

Its significance shall be established through Materiality and the Synthesis of Material Findings in relation to the Claim's Intended Function, relevant Intended Results, applicable Quality Outcome Criteria, and applicable Critical Conditions.

A Negative Conclusion shall not be established merely because a Positive Conclusion cannot be supported.

Insufficient Evidence, an Evidence gap, an Evidence Quality limitation, material Uncertainty, an unresolved matter, or inability to establish realization shall not by itself constitute affirmative support for a Negative Conclusion.

Where the available basis does not support a Positive or Conditionally Positive Conclusion but also does not affirmatively support non-realization, Refusal to Express a Conclusion shall be considered in accordance with Section 5.6.4.

A Negative Conclusion may be supported where the Evidence affirmatively establishes a material condition that prevents the Claim from realizing its Intended Function or relevant Intended Results as required, even where other Factors, Indicators, or Quality Outcome Criteria are favorably realized.

Such favorable Findings shall not compensate for a material Non-Compensable condition or an applicable Critical Condition whose non-realization affirmatively prevents the required Function Realization.

A Negative Conclusion does not require that every Quality Factor, Quality Indicator, or Quality Outcome Criterion be unfavorably realized.

Nor shall a Negative Conclusion be based on counting, averaging, weighting, or netting favorable and unfavorable Findings unless an applicable basis establishes a justified method consistent with this Core. Such a method shall not conceal a material Non-Compensable condition or change the distinct determination functions of the applicable Factors and Indicators.

The scope of a Negative Conclusion shall remain bounded by what the applicable Findings and their Synthesis affirmatively support.

Where non-realization is established only for a bounded part, condition, purpose, recipient, Context, time, or other aspect of the Claim, the Negative Conclusion shall not be extended beyond that supported scope.

A Negative Conclusion concerning the Quality State of the Claim shall remain distinct from any Negative Conclusion concerning the original Quality Object.

A Claim may accurately and appropriately communicate a Negative Conclusion or unfavorable Findings concerning the original Quality Object while itself realizing its Intended Function. In such a case, the unfavorable Quality State of the original Quality Object does not provide a basis for a Negative Conclusion concerning Claim Quality.

Conversely, a Claim concerning a favorable Quality State of the original Quality Object may support a Negative Conclusion concerning its own Quality State where affirmative Findings establish that the Claim materially misstates, exceeds, omits, distorts, renders inapplicable, or communicates unintelligibly what has been established.

Where the Claim appropriately communicates particular Findings without an overall Conclusion concerning the original Quality Object, absence of such an overall Conclusion shall not provide a basis for a Negative Conclusion concerning Claim Quality unless that Conclusion is material to the Claim's Intended Function or otherwise required by the Applicable Basis.

The possibility that the Claim could be corrected, supplemented, reformulated, reissued, or otherwise improved in the future shall not by itself alter a Negative Conclusion supported by the current applicable Findings.

Where the Findings instead support realization subject to an identified material condition to be fulfilled in the future, the requirements for a Conditionally Positive Conclusion shall be considered.

Where Harm, Risk, or Safety information is material to the Claim, a Negative Conclusion concerning Claim Quality may be supported where affirmative Findings establish that the Claim's treatment of that information materially prevents realization of its Intended Function under the applicable Quality Outcome Criteria.

Such a Negative Conclusion concerns the Quality State of the Claim. It does not by itself establish Harm, determine Risk, establish lack of Safety, or alter any separately established Harm, Risk, or Safety determination concerning the original Quality Object or another subject.

Material Uncertainty shall remain visible in a Negative Conclusion to the extent that it limits the scope or certainty of what has affirmatively been established.

Uncertainty shall not be used to extend an affirmative Finding of non-realization beyond what the Evidence supports.

The basis for a Negative Conclusion concerning the Quality State of the Claim shall remain Traceable to the Synthesis of Material Findings and to the applicable Findings, Quality Outcome Criteria, Evidence, material conditions and limitations, Critical Conditions, Non-Compensable conditions, and Uncertainty upon which the Conclusion depends.

5.6.4 Refusal to Express a Conclusion

Refusal to Express a Conclusion concerning the Quality State of the Quality Claim shall be used where the available basis does not support expression of a Positive, Conditionally Positive, or Negative Conclusion concerning the Claim as the defined Quality Object.

Refusal to Express a Conclusion is not a substantive Conclusion concerning the Quality State of the Claim.

It shall not be interpreted as establishing favorable, unfavorable, or other Quality of the Claim.

Refusal shall be based on an identified limitation in what can responsibly be established through the Quality Determination.

The basis for Refusal may include, as applicable:

- insufficient Evidence to establish one or more Findings material to the permissible Conclusion;
- an Evidence Quality limitation that prevents the available Evidence from supporting the required scope or certainty of a material Finding;
- an Evidence gap affecting a material part of the determination;
- material Uncertainty that prevents a supportable substantive Conclusion;
- an unresolved material condition or relationship;
- unresolved status of an applicable Critical Condition;
- inability to establish the applicability or realization of a material Quality Outcome Criterion;
- inability to determine a material interaction among Quality Factors or Quality Indicators;

- a material limitation in the Applicable Basis or Reference Layer affecting what can responsibly be determined; or
- another identified limitation that prevents the Synthesis of Material Findings from supporting a substantive Conclusion concerning the Quality State of the Claim.

The reason or reasons for Refusal shall be stated sufficiently to make clear why a substantive Conclusion cannot responsibly be expressed.

Refusal shall not convert the absence of a supportable Finding into an unfavorable Finding.

Similarly, inability to support a Positive Conclusion shall not be treated as support for a Negative Conclusion merely to avoid Refusal.

Where affirmative Findings support non-realization of the Claim's Intended Function or relevant Intended Results as required, a Negative Conclusion shall not be replaced by Refusal merely because the unfavorable determination is undesirable or because future correction may be possible.

Where affirmative Findings support realization subject to one or more identified material conditions to be fulfilled in the future, a Conditionally Positive Conclusion shall not be replaced by Refusal solely because those conditions remain to be fulfilled.

Refusal is appropriate where the limitation concerns what can presently be established, rather than where the applicable Findings affirmatively support realization, conditional realization, or non-realization as required for a substantive Conclusion.

Findings that can responsibly be established shall remain Findings notwithstanding the Refusal.

Refusal shall therefore be bounded to the Conclusion that cannot responsibly be expressed and shall not erase, invalidate, or conceal applicable Evidence-Supported Findings.

Where material Findings can be communicated responsibly despite Refusal, they shall remain available for the applicable use to the extent supported by the Evidence and permitted by the Claim's Intended Function, recipient, purpose, Context, and Applicable Basis.

A Refusal concerning the Quality State of the Claim shall remain distinct from any Refusal to Express a Conclusion concerning the original Quality Object.

A Quality Claim may appropriately communicate a Refusal concerning the original Quality Object and nevertheless support a Positive Conclusion concerning its own Quality State where the Claim accurately, materially sufficiently, applicably, and intelligibly communicates that Refusal and its material basis.

Conversely, the original Quality Determination may support a substantive Conclusion concerning the original Quality Object while the separate determination of Claim Quality results in Refusal because the available Evidence concerning the Claim itself is insufficient to support a substantive Conclusion about the Claim's Quality State.

Where the Claim appropriately communicates particular Evidence-Supported Findings concerning the original Quality Object without expressing an overall Conclusion or Refusal concerning that object, the absence of an original-object Conclusion or Refusal shall not be treated as Refusal and shall not provide a basis for Refusal concerning Claim Quality.

Refusal concerning Claim Quality arises only where the Quality Determination of the Claim does not provide a sufficient basis for a Positive, Conditionally Positive, or Negative Conclusion concerning the Quality State of the Claim.

Where Harm, Risk, or Safety information is material, limitations in what can be established about the Claim's treatment of that information may contribute to Refusal where they prevent a supportable substantive Conclusion concerning Claim Quality.

Refusal concerning Claim Quality shall not itself be interpreted as establishing Harm, Risk, lack of Safety, or any other substantive determination concerning the original Quality Object or another subject.

Material Uncertainty supporting Refusal shall remain visible to the extent necessary to explain what cannot responsibly be established and why.

The Refusal and its material basis shall remain Traceable to the Synthesis of Material Findings, applicable Evidence-Supported Findings, Quality Outcome Criteria, Evidence and Evidence Quality limitations, Critical Conditions, unresolved matters, and Uncertainty upon which the Refusal depends.

6. Quality Claim Core Requirements

6.1 General Requirements

A Quality Claim shall be treated as a defined Quality Object for purposes of determining its Quality under this Core.

The Quality Claim shall have a defined Intended Function and, where applicable, relevant Intended Results.

The Claim shall be considered within its defined Boundary and Interfaces and in relation to its intended recipient, intended purpose, relevant Context, Applicable Basis, and Reference Layer.

The Claim shall realize its Intended Function and relevant Intended Results through the applicable requirements of the four Quality Factors established by this Core for determining the Quality of the Claim:

- Support;
- Material Sufficiency;
- Applicability; and
- Communicative Realization.

Realization of these Quality Factors shall be determined through the seven Quality Indicators established by this Core for determining the Quality of the Claim:

- Substantive Support;
- Preservation of Material Relationships;
- Material Information Sufficiency;
- Recipient Applicability;
- Purpose Applicability;
- Context Applicability; and
- Intelligibility.

Each applicable Quality Indicator in the determination of the Quality of the Claim shall be evaluated in relation to applicable Quality Outcome Criteria.

Applicable Quality Outcome Criteria for determining the Quality of the Claim may be established by:

- this Core, where a criterion is sufficiently invariant for application across Quality Claims;
- an applicable Context Guide; or
- another justified application-specific basis consistent with the Applicable Basis and Reference Layer.

The source and applicability of the Quality Outcome Criteria used in determining the Quality of the Claim shall remain Traceable.

The Claim shall be supported by applicable Evidence-Supported Findings concerning the original Quality Object to the extent required by the Claim's Intended Function.

The substantive meaning communicated by the Claim shall not exceed, increase the certainty of, or otherwise materially alter what the applicable Findings concerning the original Quality Object support.

The Claim shall preserve material relationships necessary to maintain the supportable meaning of those Findings.

The Claim shall communicate, or provide appropriate access through defined Interfaces to, information material to realization of its Intended Function and relevant Intended Results.

The Claim shall be applicable to its intended recipient, intended purpose, and relevant Context.

The Claim shall communicate its material meaning with sufficient Intelligibility for its intended use.

A Quality Claim shall not be required to communicate all available Evidence, Findings, supporting information, or other information concerning the original Quality Object unless such information is

material to realization of the Claim's Intended Function or is otherwise required by the Applicable Basis.

A Quality Claim shall not be required to express an overall Conclusion or Refusal to Express a Conclusion concerning the Quality State of the original Quality Object where its Intended Function is appropriately realized through communication of particular Evidence-Supported Findings and such an overall Conclusion or Refusal is neither material nor otherwise required by the Applicable Basis.

Where the Claim does express a Conclusion or Refusal concerning the original Quality Object, that Conclusion or Refusal shall remain within what the applicable Findings and their Synthesis support and shall satisfy the applicable requirements of this Core for the Quality of the Claim.

Material conditions, limitations, Critical Conditions, and Uncertainty affecting the Quality of the Claim shall remain visible to the extent necessary for realization of the Claim's Intended Function and relevant Intended Results.

Where Harm, Risk, or Safety information concerning the original Quality Object or another subject is material to realization of the Claim's Intended Function, the Claim shall preserve the applicable distinctions among Quality, Harm, Risk, and Safety and shall communicate or provide appropriate access to that information to the extent required by the applicable Quality Outcome Criteria for the Claim.

The Claim shall not represent Possible Harm as Risk without the applicable determination of probability and severity, and shall not represent Risk as Safety or lack of Safety without application of the applicable Safety criteria.

Realization of one Quality Factor, Quality Indicator, or applicable Quality Outcome Criterion in the determination of the Quality of the Claim shall not be presumed to substitute for or compensate for material non-realization of another.

No numerical averaging, weighting, scoring, or balancing among the Quality Factors or Quality Indicators used in determining the Quality of the Claim shall be presumed by this Core.

Where an applicable Context Guide or other justified application-specific basis establishes such a method for determining the Quality of the Claim, the method shall preserve the distinct determination functions established by this Core and shall not conceal a material non-realization, Critical Condition, limitation, or Uncertainty affecting the Claim.

The Claim and the basis for determining its Quality shall remain Traceable to the extent required by the applicable Quality Outcome Criteria, Intended Function, recipient, purpose, Context, and Applicable Basis.

Compliance with these General Requirements does not by itself establish realization of every Quality Factor or Quality Indicator applicable to determining the Quality of the Claim.

The specific Core requirements for Support, Material Sufficiency, Applicability, and Communicative Realization are established in Sections 6.2 through 6.5.

6.2 Support Requirements

The Quality Claim shall realize the Support Factor through Substantive Support and Preservation of Material Relationships.

Support shall be determined in relation to the Claim's Intended Function and relevant Intended Results and through the applicable Quality Outcome Criteria for determining the Quality of the Claim.

The substantive content of the Claim shall remain within what the applicable Evidence-Supported Findings concerning the original Quality Object support.

The Claim shall not:

- assert a condition, result, relationship, or meaning that is not supported by the applicable Findings;
- extend a Finding beyond its supported scope, Boundary, conditions, time, Context, or Methodological Resolution;

- increase the certainty of a Finding beyond what its evidentiary basis supports;
- convert an Evidence limitation, Evidence gap, or Uncertainty into an affirmative Finding;
- remove or alter a qualification, limitation, condition, or Uncertainty where doing so materially changes the supportable meaning of a Finding; or
- combine individually supportable statements in a manner that creates a material meaning not supported by the applicable Findings.

Where the Claim communicates only selected Findings concerning the original Quality Object, the selection shall not materially distort what those Findings support or the relationships necessary to understand their supportable meaning.

The Claim shall preserve material relationships among the applicable Findings and, where relevant, their conditions, qualifications, limitations, Uncertainty, Critical Conditions, and other information necessary to preserve their supportable meaning.

Where the supportable meaning of one Finding depends materially upon another Finding, condition, relationship, assumption, limitation, or qualification, the Claim shall preserve that dependency.

Material temporal, conditional, sequential, causal, comparative, or other relationships established through the applicable Findings shall not be removed, reversed, obscured, or materially altered by the Claim.

Where the Claim communicates a Conclusion or Refusal to Express a Conclusion concerning the original Quality Object, that Conclusion or Refusal shall remain consistent with the applicable Findings and their Synthesis.

A Positive Conclusion concerning the original Quality Object shall not be communicated where the applicable Findings and their Synthesis do not support realization as required.

A Conditionally Positive Conclusion concerning the original Quality Object shall preserve the identified material future condition or conditions upon which that Conclusion depends and shall not represent their future fulfillment as established.

A Negative Conclusion concerning the original Quality Object shall not be communicated without affirmative support in the applicable Findings for non-realization as required.

A Refusal to Express a Conclusion concerning the original Quality Object shall not be converted into a favorable or unfavorable substantive Conclusion.

Where the Claim's Intended Function does not require an overall Conclusion or Refusal concerning the original Quality Object, Support shall be determined from the substantive support and material relationships of the Findings and other information that the Claim is intended to communicate. Absence of an overall original-object Conclusion or Refusal shall not constitute lack of Support merely because the Claim communicates only particular Findings.

Where Harm, Risk, or Safety information is communicated or otherwise material to the Claim, the Claim shall preserve the substantive distinctions and material relationships established through the applicable basis for that information.

The Claim shall not represent:

- a Quality condition as Harm merely because the condition may be Harm-capable;
- Possible Harm as Realized Harm;
- Possible Harm as Risk without the applicable determination of probability and severity;
- Risk as Safety or lack of Safety without application of the applicable Safety criteria; or
- a Quality determination as a Harm, Risk, or Safety determination unless that separate determination has been established through its applicable basis.

Where material Uncertainty concerns Harm, Risk, or Safety information, the Claim shall not remove or reduce that Uncertainty beyond what the applicable determination supports.

Support does not require the Claim to reproduce all Evidence, Findings, reasoning, or supporting information concerning the original Quality Object.

Supporting information may remain outside the direct content of the Claim where access through a defined Interface preserves the material supportable meaning required for the Claim's Intended Function.

Use of an Interface shall not permit the Claim to state a substantive meaning that exceeds what the applicable Findings support or to obscure a material relationship necessary to understand that meaning.

The Claim shall remain Traceable, to the extent required by the applicable Quality Outcome Criteria, to the Findings and material relationships upon which its substantive content depends.

Realization of Material Sufficiency, Applicability, or Communicative Realization in determining the Quality of the Claim shall not substitute for non-realization of Support.

A Claim shall not be considered to realize Support merely because it is complete, useful to its recipient, applicable to its purpose or Context, intelligible, persuasive, or otherwise effectively communicated.

Support shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

6.3 Material Sufficiency Requirements

The Quality Claim shall realize the Material Sufficiency Factor through Material Information Sufficiency.

Material Sufficiency shall be determined in relation to the Claim's Intended Function and relevant Intended Results and through the applicable Quality Outcome Criteria for determining the Quality of the Claim.

The Claim shall communicate, or provide appropriate access through defined Interfaces to, the information material to realization of its Intended Function.

Material Information Sufficiency shall be determined by the significance of information to the Claim's Intended Function, not by the quantity, length, detail, or volume of information communicated.

The Claim shall include or provide appropriate access to, as applicable:

- Evidence-Supported Findings concerning the original Quality Object that are material to the Claim's Intended Function;
- conditions, qualifications, and limitations material to the meaning or use of those Findings;
- material Uncertainty;
- applicable Critical Conditions where their status is material to the Claim's Intended Function;
- a Conclusion or Refusal to Express a Conclusion concerning the original Quality Object where such a Conclusion or Refusal is material to the Claim's Intended Function or otherwise required by the Applicable Basis;
- material information concerning Harm, Risk, or Safety where such information is necessary for realization of the Claim's Intended Function; and
- other supporting information necessary for the intended recipient to use the Claim for its intended purpose within the relevant Context.

The Claim shall not be required to include or provide access to information merely because that information exists or was considered in determining the Quality State of the original Quality Object.

Information that is not material to realization of the Claim's Intended Function need not be communicated unless otherwise required by the Applicable Basis.

A Claim limited to particular Evidence-Supported Findings concerning the original Quality Object may realize Material Sufficiency without communicating an overall Conclusion or Refusal concerning that object where such a Conclusion or Refusal is not material to the Claim's Intended Function and is not otherwise required by the Applicable Basis.

Selection, summarization, compression, or omission of information shall not remove information whose absence materially prevents realization of the Claim's Intended Function or relevant Intended Results.

Brevity, format limitations, communication preferences, recipient preferences, or convenience shall not by themselves justify omission of material information.

Where information material to the Claim is maintained outside its direct content, the Claim shall provide an appropriate Interface to that information where access is necessary for realization of the Claim's Intended Function.

Such an Interface shall provide access with sufficient reliability, availability, specificity, and continuity for the material information to perform its required function in relation to the Claim.

Information shall not be treated as materially sufficient merely because it technically exists or can potentially be located elsewhere.

Where the intended recipient cannot reasonably identify, access, or associate external information with the Claim as required for its intended use, that information shall not be presumed to satisfy Material Information Sufficiency.

Where Harm, Risk, or Safety information is material to the Claim's Intended Function, that information shall not be omitted merely because Harm, Risk, and Safety are analytically distinct from Quality.

The Claim shall communicate or provide appropriate access to the material Harm, Risk, or Safety information, including material conditions, limitations, and Uncertainty, to the extent required by the applicable Quality Outcome Criteria for determining the Quality of the Claim.

Material Sufficiency does not require maximum disclosure of Harm, Risk, or Safety information. It requires the information material to realization of the Claim's Intended Function within its applicable Boundary, recipient, purpose, and Context.

Material Uncertainty shall be communicated or made appropriately accessible where omission of that Uncertainty would materially change the meaning, significance, applicability, or intended use of the Claim.

Where the materiality of information cannot be established with sufficient support, the resulting limitation or Uncertainty shall remain visible to the extent that it affects determination of Material Information Sufficiency.

Material Sufficiency shall remain distinct from Support.

Information may be substantively supported but materially insufficient where information necessary for realization of the Claim's Intended Function is omitted or inaccessible.

Conversely, extensive information does not realize Material Sufficiency where material information is absent, obscured, disconnected from the Claim, or otherwise unavailable for its required function.

Material Sufficiency shall also remain distinct from Intelligibility.

The presence or accessibility of material information does not by itself establish that the information is communicated with sufficient Intelligibility, and Intelligibility does not compensate for absence of material information.

Realization of Support, Applicability, or Communicative Realization in determining the Quality of the Claim shall not substitute for material non-realization of Material Sufficiency.

The Claim shall remain Traceable, to the extent required by the applicable Quality Outcome Criteria, to the basis for determining which information is material to realization of its Intended Function and relevant Intended Results.

Material Sufficiency shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

6.4 Applicability Requirements

The Quality Claim shall realize the Applicability Factor through Recipient Applicability, Purpose Applicability, and Context Applicability.

Applicability shall be determined in relation to the Claim's Intended Function and relevant Intended Results and through the applicable Quality Outcome Criteria for determining the Quality of the Claim.

The Claim shall be applicable to:

- its intended recipient;
- its intended purpose; and
- the relevant Context.

These three aspects of Applicability shall remain distinguishable in determining the Quality of the Claim.

Realization of one shall not be presumed to establish realization of another.

Recipient Applicability

The Claim shall provide its intended recipient with information in a form and at a level appropriate to the recipient's role and to realization of the Claim's Intended Function.

Recipient Applicability shall consider, as applicable:

- the recipient's defined role in relation to the Claim;
- the information the recipient requires for the Claim's intended use;
- the level of detail and Methodological Resolution required for that use;
- terminology, qualifications, conditions, limitations, and Uncertainty material to the recipient's use of the Claim;
- material Harm, Risk, or Safety information;
- access to material supporting information through defined Interfaces; and
- requirements established by the Applicable Basis for communication to that recipient.

Differences among recipients may justify different expressions of the same applicable Findings where those expressions remain within what the Findings support and preserve material relationships and information.

Recipient preferences shall not justify alteration of substantive support, concealment of material information, removal of material Uncertainty, or other changes that prevent realization of applicable Claim Quality requirements.

Purpose Applicability

The Claim shall be suitable for the purpose for which it is intended to be used.

Purpose Applicability shall consider, as applicable:

- the decision, action, understanding, communication, or other use for which the Claim is intended;
- the Findings and material information necessary for that use;
- the Methodological Resolution required for that use;
- conditions, limitations, Critical Conditions, and Uncertainty material to that use;
- material Harm, Risk, or Safety information;
- applicable Interfaces and supporting information; and
- requirements established by the Applicable Basis for the intended purpose.

A Claim applicable to one purpose shall not be presumed applicable to another purpose.

A change in intended purpose may change what information is material, the applicable Quality Outcome Criteria, required Methodological Resolution, applicable Critical Conditions, or necessary Interfaces.

A change in purpose shall not expand what the Findings concerning the original Quality Object support or increase their supported certainty.

Where the Claim is used for a purpose outside its defined Intended Function, applicability to that additional purpose shall not be presumed from its Quality Determination for the original purpose.

Context Applicability

The Claim shall be applicable within the Context for which its Intended Function is defined.

Context Applicability shall consider, as applicable:

- the applicable time or period;
- physical, operational, organizational, regulatory, technical, social, environmental, or other circumstances material to the Claim's intended use;
- the Applicable Basis and Reference Layer;
- assumptions and conditions upon which applicability depends;
- applicable Critical Conditions;
- material changes affecting the Claim or the original Quality Object;
- defined Interfaces and external dependencies; and
- material Harm, Risk, or Safety conditions and associated Uncertainty.

A Claim determined to be applicable within one Context shall not be presumed applicable within another materially different Context.

A Claim shall not be presumed currently applicable merely because it was applicable when originally made or when the underlying Findings concerning the original Quality Object were established.

Where time is material to applicability, the temporal Boundary of the Claim shall remain identifiable.

Where a material change in Context occurs, the continued applicability of the Claim shall be reconsidered to the extent required by the applicable Quality Outcome Criteria.

A change in Context does not itself alter the Findings previously established concerning the original Quality Object.

It may, however, change whether those Findings, or a Claim based upon them, remain applicable for the Claim's intended recipient, purpose, or use.

Where the Applicable Basis, Reference Layer, Boundary, assumptions, or other conditions material to the Claim's Context change, the effect of that change on Context Applicability shall be determined rather than presumed.

Where Harm, Risk, or Safety information is material to Applicability, the Claim shall preserve the applicable Context for any probability, severity, acceptability, tolerability, or other conditions upon which the relevant determination depends.

A Harm, Risk, or Safety determination established for one Context shall not be presumed applicable to another materially different Context.

Applicability shall remain distinct from Support, Material Sufficiency, and Communicative Realization.

A Claim may be substantively supported and materially sufficient yet fail to realize Applicability for a particular recipient, purpose, or Context.

Conversely, suitability for a recipient, purpose, or Context shall not compensate for substantive content that exceeds what the applicable Findings support, omission of material information, or insufficient Intelligibility.

Realization of Support, Material Sufficiency, or Communicative Realization in determining the Quality of the Claim shall not substitute for material non-realization of an applicable aspect of Applicability.

The Claim shall remain Traceable, to the extent required by the applicable Quality Outcome Criteria, to the recipient, purpose, Context, assumptions, conditions, and other basis upon which its Applicability depends.

Applicability shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

6.5 Communicative Realization Requirements

The Quality Claim shall realize the Communicative Realization Factor through Intelligibility.

Communicative Realization shall be determined in relation to the Claim's Intended Function and relevant Intended Results and through the applicable Quality Outcome Criteria for determining the Quality of the Claim.

The Claim shall communicate its material meaning with sufficient Intelligibility for its intended recipient to understand and use the Claim for its intended purpose within the relevant Context.

Intelligibility shall concern the communication of material meaning, not merely the readability, simplicity, brevity, visual presentation, or linguistic form of the Claim.

The Claim shall communicate, to the extent material to realization of its Intended Function:

- what is being claimed or otherwise communicated;
- the original Quality Object or other subject to which the communicated information relates;
- the applicable Finding or Findings upon which the substantive content of the Claim depends;
- material conditions, qualifications, and limitations;
- material Uncertainty;
- applicable Critical Conditions where their status is necessary to understand the Claim;
- the scope, Boundary, time, or Context necessary to understand the applicability of the Claim;
- any Conclusion or Refusal to Express a Conclusion concerning the original Quality Object where such a Conclusion or Refusal forms part of the Claim;
- material Harm, Risk, or Safety information; and
- the function of any Interface through which material supporting information must be accessed.

The Claim shall communicate distinctions among materially different types of information where failure to preserve those distinctions could change or obscure its meaning.

In particular, the Claim shall distinguish, where applicable, among:

- Evidence and Evidence-Supported Findings;
- established conditions and assumptions;
- current conditions and future conditions;
- Findings and Conclusions;
- a substantive Conclusion and Refusal to Express a Conclusion;
- limitations in what has been established and affirmative Findings of non-realization;
- the Quality State of the original Quality Object and the Quality State of the Claim as a separate Quality Object; and
- Quality, Harm, Risk, and Safety.

Where the Claim communicates a Positive, Conditionally Positive, or Negative Conclusion concerning the original Quality Object, or a Refusal to Express a Conclusion concerning that object, the nature and scope of that communication shall be sufficiently intelligible to avoid material ambiguity concerning what has been established.

Where a Conditionally Positive Conclusion concerning the original Quality Object is communicated, the material future condition or conditions upon which that Conclusion depends shall be distinguishable from conditions already established as realized.

The Claim shall not communicate a Refusal to Express a Conclusion concerning the original Quality Object in a manner that materially implies either a favorable or unfavorable substantive Conclusion.

Where the Claim appropriately communicates particular Evidence-Supported Findings without an overall Conclusion or Refusal concerning the original Quality Object, the Claim shall make the material meaning and scope of those Findings sufficiently intelligible for its Intended Function.

Absence of an overall Conclusion or Refusal concerning the original Quality Object shall not constitute insufficient Intelligibility where such a Conclusion or Refusal is not material to the Claim's Intended Function and is not otherwise required by the Applicable Basis.

Terminology, structure, level of detail, form of expression, and presentation shall be suitable to communicate the material meaning required by the Claim's Intended Function.

Technical terminology may be used where appropriate to the intended recipient, purpose, and Context. Simplification or translation into less technical language may be used where appropriate, provided that the substantive meaning, material relationships, conditions, limitations, and Uncertainty are not materially altered or lost.

Clarity shall not be achieved by removing information or distinctions whose absence changes the material meaning of the Claim.

Where information necessary to understand the Claim is provided through an Interface, the relationship between the Claim and that information shall be sufficiently identifiable for the intended recipient to recognize what information is available and its relevance to the Claim.

An Interface shall not be treated as communicatively realized merely because the supporting information technically exists.

Where use of the Interface is necessary to understand the material meaning of the Claim, the Interface shall permit that relationship and information to be understood to the extent required by the applicable Quality Outcome Criteria.

Where Harm, Risk, or Safety information is material to the Claim, the Claim shall communicate that information without materially obscuring the distinctions among:

- a Harm-capable condition;
- a Harm pathway;
- Possible Harm;
- Conditions of Materialization;
- Realized Harm;
- Risk; and
- Safety,

to the extent those distinctions are applicable to the Claim's Intended Function.

The communication of Possible Harm shall not materially imply that Harm has been realized.

The communication of Possible Harm shall not materially imply a Risk determination where probability and severity have not been determined through the applicable basis.

The communication of Risk shall not materially imply Safety or lack of Safety without application of the applicable Safety criteria.

Material Uncertainty concerning Quality, Harm, Risk, or Safety shall be communicated with sufficient Intelligibility to preserve what is and is not established.

Communicative Realization shall remain distinct from Support, Material Sufficiency, and Applicability.

A Claim may contain substantively supported and materially sufficient information and be applicable to its recipient, purpose, and Context, yet fail to realize Communicative Realization where its material meaning cannot be sufficiently understood for its intended use.

Conversely, a Claim that is clear, concise, understandable, persuasive, or well presented shall not be considered to realize Communicative Realization where the meaning communicated is unsupported, materially insufficient, or inapplicable.

Realization of Support, Material Sufficiency, or Applicability in determining the Quality of the Claim shall not substitute for material non-realization of Communicative Realization.

Intelligibility does not require a single communication form, terminology, structure, level of technical detail, or presentation method for all Quality Claims.

The required level and form of Intelligibility shall be established through the applicable Quality Outcome Criteria in relation to the Claim's Intended Function, intended recipient, intended purpose, relevant Context, and Applicable Basis.

The Claim shall remain Traceable, to the extent required by the applicable Quality Outcome Criteria, to the basis for determining the communication requirements material to realization of its Intended Function and relevant Intended Results.

Communicative Realization shall be determined through the applicable Quality Outcome Criteria established by this Core, an applicable Context Guide, or another justified application-specific basis.

7. Application and Contextualization

7.1 Invariant Core Structure

This Core establishes the invariant methodological structure for determining the Quality of a Quality Claim as a defined Quality Object.

The invariant structure consists of the four Quality Factors:

- Support;
- Material Sufficiency;
- Applicability; and
- Communicative Realization;

and the seven Quality Indicators:

- Substantive Support;
- Preservation of Material Relationships;
- Material Information Sufficiency;
- Recipient Applicability;
- Purpose Applicability;
- Context Applicability; and
- Intelligibility.

These Quality Factors and Quality Indicators shall retain their established determination functions when this Core is applied to different classes, purposes, recipients, Contexts, domains, or forms of Quality Claims.

Contextualization shall not add, remove, rename, merge, divide, or redefine a Core Quality Factor or Quality Indicator in a manner that changes its determination function.

Where an application requires examination of a more specific condition, characteristic, relationship, or requirement, that specificity shall normally be established through applicable Quality Outcome Criteria, Critical Conditions, or other application provisions rather than through creation of an additional Core Quality Factor or Quality Indicator.

The invariant Core structure does not require identical Quality Outcome Criteria, Evidence, Evidence Quality requirements, Critical Conditions, methods, thresholds, levels of Methodological Resolution, communication forms, or supporting Interfaces for all Quality Claims.

Those matters may vary where justified by the Claim's Intended Function, relevant Intended Results, intended recipient, intended purpose, Context, Applicable Basis, Reference Layer, and other applicable conditions.

Such variation shall not change the determination function of the Core Quality Factor or Quality Indicator to which the contextualized provision applies.

The invariant structure shall be applied to the Quality Claim as the Quality Object under determination.

The determination of the original Quality Object and the determination of the Claim shall remain distinct. Accordingly, Quality Factors, Quality Indicators, Quality Outcome Criteria, Findings, Critical Conditions, and Conclusions belonging to the original-object determination do not become Claim-quality elements merely because the Claim communicates them.

Information from the original-object determination may provide substantive or evidentiary input to the Claim-quality determination where applicable. The two determinations shall nevertheless remain distinguishable and Traceable.

The invariant Core structure shall apply whether the Quality Claim communicates:

- one or more particular Evidence-Supported Findings concerning the original Quality Object;
- a broader set or synthesis of Findings;
- a Positive, Conditionally Positive, or Negative Conclusion concerning the original Quality Object;
- a Refusal to Express a Conclusion concerning the original Quality Object; or
- another supportable communication concerning the Quality State of the original Quality Object consistent with the Claim's Intended Function and Applicable Basis.

The presence of an overall Conclusion or Refusal concerning the original Quality Object is therefore not an invariant structural requirement for every Quality Claim.

What remains invariant is that the Quality of the Claim itself is determined through the applicable Core Quality Factors and Quality Indicators in relation to the Claim's own Intended Function and relevant Intended Results.

Contextualization may establish different Quality Outcome Criteria for different classes or uses of Quality Claims where those criteria preserve the determination function of the applicable Core Quality Factor or Quality Indicator.

Contextualization may also establish application-specific Critical Conditions where justified.

A context-specific provision shall not be represented as an invariant Core requirement unless its applicability across the relevant class of Quality Claims has been established at the Methodological Resolution appropriate to this Core.

Where a proposed contextual requirement cannot be assigned consistently to an existing Core Quality Factor or Quality Indicator, the application shall first determine whether the requirement concerns:

- a Quality Outcome Criterion;
- a Critical Condition;
- Evidence or Evidence Quality;
- Materiality;
- Uncertainty;
- Traceability;
- an Interface;
- the Applicable Basis or Reference Layer; or
- another supporting or application-specific element.

Such an element shall not be treated as an additional Quality Factor or Quality Indicator merely because it is important to the determination.

Where application experience identifies a condition that appears not to be adequately addressed by the invariant Core structure, that condition shall be documented and examined through controlled methodological review rather than resolved by uncontrolled modification of the Core structure.

Any revision of the invariant Quality Factors or Quality Indicators shall be made only through controlled revision of this Core and its supporting methodological basis.

Application and contextualization shall therefore preserve a common Claim Quality structure while permitting the specificity necessary to determine the Quality of different Quality Claims under their applicable conditions.

7.2 Quality Outcome Criteria

Quality Outcome Criteria shall provide the criteria against which Evidence concerning the Quality Claim is evaluated to establish Evidence-Supported Findings under the applicable Quality Indicators.

For purposes of this Section, the Quality Outcome Criteria concern determination of the Quality of the Claim as the defined Quality Object.

They shall remain distinguishable from Quality Outcome Criteria used to determine the Quality of the original Quality Object, even where the two sets of criteria are related or draw upon common sources.

Each applicable Quality Outcome Criterion shall be associated with the Quality Factor or Quality Indicator whose determination function it supports.

A Quality Outcome Criterion shall not redefine, replace, or materially alter the determination function of the applicable Core Quality Factor or Quality Indicator.

Applicable Quality Outcome Criteria for determining the Quality of a Claim may be established through one or more of the following:

- this Core, where a criterion is sufficiently invariant for application across the relevant class of Quality Claims;
- an applicable Context Guide, where additional or more specific criteria are required for a defined class, purpose, recipient, Context, or application of Quality Claims; or
- another justified application-specific basis, where the required specificity can be established without development or application of a separate Context Guide.

A Context Guide is therefore not required for every application of this Core.

Where this Core establishes an applicable Quality Outcome Criterion, that criterion shall apply unless the Applicable Basis permits justified contextual specification or supplementation consistent with the criterion and with the determination function of the applicable Quality Factor or Quality Indicator.

A Context Guide may establish additional or more specific Quality Outcome Criteria necessary to apply the invariant Core structure to a defined class or Context of Quality Claims.

Such criteria shall remain consistent with this Core and shall not remove, weaken, or contradict an applicable Core criterion merely because a different contextual result is preferred.

Another justified application-specific basis may establish a Quality Outcome Criterion where:

- no applicable Core criterion provides the necessary specificity;
- no applicable Context Guide provides the necessary criterion, or development or use of a separate Context Guide is not required for the application;
- the criterion is supported by the Applicable Basis and, where relevant, the Reference Layer;
- the criterion is consistent with the determination function of the applicable Core Quality Factor or Quality Indicator; and
- the source, applicability, and justification of the criterion remain Traceable.

Application-specific Quality Outcome Criteria may be derived or justified through applicable laws, regulations, standards, contractual requirements, technical requirements, scientific or professional knowledge, organizational requirements, defined recipient or purpose requirements, or other sources included within or supported by the Applicable Basis and Reference Layer.

The existence of such a source does not by itself establish a Quality Outcome Criterion.

The application shall establish how the source provides or supports a criterion relevant to realization of the Claim's Intended Function or relevant Intended Results through the applicable Quality Factor or Quality Indicator.

Quality Outcome Criteria shall be sufficiently defined to permit Evidence to be evaluated and an Evidence-Supported Finding to be established at the applicable Methodological Resolution.

A criterion shall not be treated as realized merely because Evidence relevant to the criterion exists.

The determination pathway shall remain:

Quality Indicator

↓

Applicable Quality Outcome Criterion

↓

Evidence

↓

Evidence-Supported Finding

Where more than one Quality Outcome Criterion applies to an Indicator, each criterion shall retain its applicable determination function and material relationship to the resulting Findings.

Realization of one applicable criterion shall not automatically establish realization of another.

Nor shall realization of one criterion compensate for material non-realization of another unless the Applicable Basis expressly establishes a relationship permitting such treatment and that relationship remains consistent with the Non-Substitutability and Non-Compensability requirements of this Core.

Where criteria established through different sources apply to the same determination, their relationship and order of applicability shall be established through the Applicable Basis.

A more specific criterion may supplement or particularize a more general criterion where the two are consistent and the more specific criterion does not change the determination function established by this Core.

Where an apparent conflict exists among applicable Quality Outcome Criteria, the conflict shall not be resolved through arbitrary selection, averaging, or omission.

The applicable basis for resolving the conflict, including any governing hierarchy, jurisdictional requirement, contractual priority, or other controlling relationship, shall be established and remain Traceable.

Where the conflict cannot be resolved sufficiently to permit a responsible Finding, the resulting limitation or Uncertainty shall remain visible and shall be considered in the Quality Determination of the Claim.

Quality Outcome Criteria may establish qualitative, quantitative, categorical, conditional, threshold-based, or other requirements where appropriate to the applicable determination function and supported by the Applicable Basis.

This Core does not presume a universal scoring, weighting, grading, or threshold system for Claim Quality.

Where a Context Guide or another justified application-specific basis establishes such a system, it shall preserve the distinct determination functions of the Core Quality Factors and Quality Indicators and shall not conceal material non-realization, Critical Conditions, limitations, or Uncertainty.

Quality Outcome Criteria concerning Harm, Risk, or Safety information shall preserve the distinctions among Quality, Harm, Risk, and Safety.

A criterion concerning the Claim's treatment of Harm, Risk, or Safety information is a criterion for determining the Quality of the Claim. It shall not be treated as a Harm, Risk, or Safety criterion for the original Quality Object unless that separate criterion has been established through its applicable basis.

The Quality Outcome Criteria applied in determining the Quality of the Claim, their sources, their relationship to the applicable Quality Factors and Quality Indicators, and any material contextualization, supplementation, hierarchy, or limitation shall remain Traceable.

The use of contextualized Quality Outcome Criteria shall therefore provide the specificity necessary for application of this Core while preserving the invariant Claim Quality structure established in Section 7.1.

7.3 Context-Specific Critical Conditions

Context-specific Critical Conditions may be established where a condition is of such significance that its absence, non-achievement, violation, failure, or unresolved status prevents a responsible Positive

Conclusion or otherwise materially constrains the permissible Conclusion concerning the Quality State of the Claim.

For purposes of this Section, the Critical Conditions concern determination of the Quality of the Claim as the defined Quality Object.

They shall remain distinguishable from Critical Conditions applicable to determination of the Quality of the original Quality Object, even where a Critical Condition concerning the original Quality Object is material to the Claim.

A Critical Condition concerning the original Quality Object does not automatically become a Critical Condition concerning the Quality of the Claim.

Its treatment may, however, become material to Claim Quality where the Claim's Intended Function requires that the condition, its status, its implications, or associated Uncertainty be appropriately supported, materially sufficient, applicable, or intelligibly communicated.

Context-specific Critical Conditions for Claim Quality may be established through:

- an applicable Context Guide;
- the Applicable Basis or Reference Layer;
- applicable Quality Outcome Criteria; or
- another justified application-specific basis consistent with this Core.

This Core does not presume a universal set of Critical Conditions applicable to all Quality Claims.

A condition shall not be designated a Critical Condition merely because it is important, desirable, relevant, or associated with an unfavorable Finding.

Designation as a Critical Condition shall require a justified basis for determining that the condition materially constrains the permissible Conclusion concerning the Quality State of the Claim.

A context-specific Critical Condition may concern, as applicable:

- Substantive Support;
- Preservation of Material Relationships;
- Material Information Sufficiency;
- Recipient Applicability;
- Purpose Applicability;
- Context Applicability;
- Intelligibility;
- a material Interface or dependency necessary for realization of the Claim's Intended Function;
- a material limitation or condition affecting Evidence or Evidence Quality;
- material Uncertainty;
- a requirement established by the Applicable Basis; or
- treatment of material Harm, Risk, or Safety information.

A Critical Condition shall remain associated with the applicable Quality Factor, Quality Indicator, Quality Outcome Criterion, or other determination element through which its significance is established.

A Critical Condition shall not be treated as an additional Quality Factor or Quality Indicator.

Where the same Critical Condition affects more than one Quality Factor or Quality Indicator, its effects may be examined through each applicable determination function without treating the condition as multiple independent Critical Conditions merely because it has multiple effects.

The basis for designating a condition as Critical shall identify, to the extent applicable:

- the condition itself;
- the source or basis establishing its significance;
- the Quality Factor, Quality Indicator, Quality Outcome Criterion, or other determination element affected;

- the Claim's Intended Function or relevant Intended Result to which the condition is material;
- the circumstances under which the condition applies;
- the status of the condition;
- the effect of its absence, non-achievement, violation, failure, or unresolved status on the permissible Conclusion; and
- material limitations or Uncertainty concerning that effect.

The status of an applicable Critical Condition shall be established through Evidence-Supported Findings to the extent necessary for its use in the Quality Determination of the Claim.

Non-realization of a Critical Condition shall not automatically establish a Negative Conclusion.

A Negative Conclusion requires affirmative support in the material Findings and their Synthesis that the Claim does not realize its Intended Function or relevant Intended Results as required under the applicable Quality Outcome Criteria.

Where non-realization of a Critical Condition affirmatively establishes such non-realization, the condition may support a Negative Conclusion.

Where the status or effect of a Critical Condition cannot be established sufficiently to support a substantive Conclusion, the resulting limitation or Uncertainty shall not be converted into an affirmative Finding of non-realization.

Where that limitation prevents support for a Positive, Conditionally Positive, or Negative Conclusion, Refusal to Express a Conclusion may be required.

An unresolved Critical Condition shall not automatically exclude a Conditionally Positive Conclusion.

Where the Findings support realization of the Claim's Intended Function and relevant Intended Results subject to future fulfillment of an identified material Critical Condition, a Conditionally Positive Conclusion may be appropriate where the requirements of Section 5.6.2 are satisfied.

The existence of the Critical Condition shall not itself establish that the future condition will be fulfilled.

Where a Critical Condition concerns information about the original Quality Object, the Claim shall treat that condition according to the requirements applicable to the Quality of the Claim.

For example, a material Critical Condition concerning the original Quality Object may require appropriate preservation of its status under Support, communication under Material Sufficiency, consideration under Applicability, or clear expression under Communicative Realization.

This treatment does not transfer the original-object Critical Condition into the Claim-quality determination as the same determination element unless a justified basis separately establishes it as a Critical Condition for Claim Quality.

Where Harm, Risk, or Safety information is material, a context-specific Critical Condition may concern the Claim's treatment of that information.

Such a Critical Condition shall concern realization of the Claim's Intended Function and shall not itself establish Harm, determine Risk, or establish Safety or lack of Safety concerning the original Quality Object or another subject.

Material Uncertainty concerning the existence, status, applicability, or effect of a Critical Condition shall remain visible in the Quality Determination of the Claim.

A Critical Condition shall not be presumed resolved merely because other Quality Factors, Quality Indicators, or Quality Outcome Criteria are favorably realized.

Nor shall favorable realization elsewhere compensate for a Critical Condition where the applicable basis establishes that the condition materially constrains the permissible Conclusion.

The Critical Condition, its basis, applicability, status, relationship to the applicable Quality Factors, Quality Indicators, and Quality Outcome Criteria, and its effect on the permissible Conclusion shall remain Traceable.

Context-specific Critical Conditions shall therefore provide a controlled means of recognizing conditions that materially constrain the permissible Conclusion without altering the invariant Quality Factors and Quality Indicators established by this Core.

7.4 Context Guides and Other Applications

This Core may be applied directly or through an applicable Context Guide or another justified application-specific basis.

A Context Guide may be developed where a defined class, purpose, recipient, Context, or application of Quality Claims requires recurring contextual provisions that are not sufficiently established by this Core alone.

A Context Guide shall apply the invariant Quality Factors and Quality Indicators established by this Core without changing their determination functions.

A Context Guide may establish or specify, as applicable:

- the class or type of Quality Claims to which the Guide applies;
- the applicable Intended Function and relevant Intended Results, or requirements for their determination;
- relevant Boundaries and Interfaces;
- the intended recipient or classes of recipients;
- the intended purpose or purposes;
- the applicable Context;
- the Applicable Basis and Reference Layer;
- context-specific Quality Outcome Criteria;
- context-specific Critical Conditions;
- Evidence and Evidence Quality requirements;
- applicable Methodological Resolution;
- requirements concerning Materiality, Uncertainty, and Traceability;
- requirements for treatment of Harm, Risk, or Safety information;
- communication, accessibility, or Interface requirements; and
- other application provisions necessary to determine the Quality of the applicable class of Claims.

A Context Guide shall not add, remove, rename, merge, divide, or redefine a Core Quality Factor or Quality Indicator in a manner that changes its determination function.

Where additional specificity is required, that specificity shall be established through Quality Outcome Criteria, Critical Conditions, or other controlled application provisions rather than through creation of additional Core Quality Factors or Quality Indicators.

A Context Guide shall distinguish requirements for determining the Quality of the Claim from requirements, Findings, Quality Outcome Criteria, Critical Conditions, Conclusions, or other determination elements concerning the original Quality Object.

Where information from the determination of the original Quality Object is used in determining Claim Quality, the relationship between the two determinations shall remain distinguishable and Traceable.

A Context Guide may establish Quality Outcome Criteria that supplement or particularize criteria established by this Core where additional specificity is necessary for the applicable class or Context of Claims.

Such contextualization shall remain consistent with Section 7.2 and shall not change the determination function of the applicable Core Quality Factor or Quality Indicator.

A Context Guide may establish context-specific Critical Conditions in accordance with Section 7.3.

Such Critical Conditions shall not be treated as additional Core Quality Factors or Quality Indicators.

Development or use of a separate Context Guide is not required where the Quality of a Claim can be responsibly determined through this Core together with applicable Quality Outcome Criteria and other necessary provisions established through a justified application-specific basis.

An application-specific basis may be appropriate for an individual Claim, a limited application, or another situation in which development of a recurring Context Guide is not methodologically necessary.

Such an application-specific basis shall remain consistent with this Core and shall identify and justify the provisions necessary for the determination.

Where an application-specific provision performs the same function as a provision that could otherwise be established through a Context Guide, use of the application-specific basis shall not reduce the methodological requirements applicable to that provision.

The absence of a Context Guide shall not permit omission of a Quality Outcome Criterion, Critical Condition, Evidence requirement, material limitation, Interface requirement, or other provision necessary for a responsible determination of Claim Quality.

Conversely, a Context Guide shall not introduce requirements that are unrelated to realization of the applicable Claim's Intended Function or relevant Intended Results merely for the purpose of increasing detail or uniformity.

Context Guides and other applications may differ in their required Evidence, Evidence Quality, Methodological Resolution, Quality Outcome Criteria, Critical Conditions, communication forms, Interfaces, or other contextual provisions where those differences are justified by the applicable Claims and their Contexts.

Such differences do not alter the invariant Core structure.

Where a Context Guide or another application establishes quantitative thresholds, classifications, scoring, weighting, aggregation, or other combined evaluation methods, those methods shall remain consistent with the Non-Substitutability and Non-Compensability requirements of this Core.

They shall not conceal material non-realization, an applicable Critical Condition, material Uncertainty, or another condition that materially constrains the permissible Conclusion concerning the Quality State of the Claim.

Where Harm, Risk, or Safety information is material to an application, the Context Guide or other application-specific basis may establish requirements for the Claim's treatment of that information.

Such provisions shall preserve the distinctions among Quality, Harm, Risk, and Safety and shall not convert determination of Claim Quality into a Harm, Risk, or Safety determination concerning the original Quality Object or another subject.

Context Guides and other applications may specify forms, structures, terminology, reporting arrangements, supporting records, or Interfaces appropriate to their intended recipients, purposes, and Contexts.

Such specifications shall support realization of the applicable Claim Quality requirements and shall not be treated as ends independent of the Claim's Intended Function.

Conformance with a prescribed form or template shall not by itself establish realization of Claim Quality.

Similarly, departure from a particular form or template shall not by itself establish non-realization unless that form or template is required by the Applicable Basis or the departure materially prevents realization of the Claim's Intended Function or relevant Intended Results.

Where application experience identifies recurring conditions not adequately addressed by an existing Context Guide or application-specific basis, those conditions shall be documented and considered through controlled revision of the applicable document.

Where application experience indicates a possible limitation in the invariant Core structure itself, the matter shall be addressed through controlled methodological review of this Core rather than through uncontrolled modification at the application level.

The applicable Context Guide or other application-specific basis, its relationship to this Core, and the sources and justification for its contextual provisions shall remain Traceable.

Context Guides and other justified applications shall therefore provide the specificity necessary to apply the common Claim Quality structure while preserving the invariant Quality Factors, Quality Indicators, and determination functions established by this Core.

8. Controlled Revision

This Core shall be maintained through controlled revision.

Controlled revision shall preserve the Traceability of substantive changes to the methodological structure, requirements, terminology, and application of the Core.

Revision may be considered where research, application experience, methodological analysis, changes in the WQI framework, or other relevant Evidence indicates that an existing provision requires clarification, modification, supplementation, or removal.

Revision shall distinguish between:

- changes to the invariant Core structure;
- changes to Core requirements that do not alter the invariant Quality Factors or Quality Indicators;
- changes to Quality Outcome Criteria established by the Core;
- changes appropriate to a Context Guide or another application-specific basis; and
- editorial changes that do not alter methodological or normative meaning.

A condition identified in a particular application shall not be incorporated into the invariant Core merely because it is important within that application.

Before an application-derived condition is incorporated into the Core, its relevance to the applicable class of Quality Claims and its relationship to the existing Core structure shall be examined at an appropriate Methodological Resolution.

Where the condition can be adequately addressed through an existing Quality Factor or Quality Indicator by means of a Quality Outcome Criterion, Critical Condition, Context Guide provision, or another justified application-specific provision, creation or modification of an invariant Core Quality Factor or Quality Indicator shall not be presumed necessary.

A proposed change to the four Quality Factors or seven Quality Indicators shall require methodological examination of whether the change:

- represents a distinct determination function not adequately represented by the existing structure;
- can be absorbed without loss into an existing Quality Factor or Quality Indicator;
- duplicates an existing determination function;
- improperly elevates a supporting concept, Quality Outcome Criterion, Critical Condition, Interface, or application provision into a Quality Factor or Quality Indicator;
- remains applicable across the intended class of Quality Claims;
- preserves necessary distinctions among the existing determination functions; and
- is supported at the Methodological Resolution appropriate to the Core.

Such examination shall, where applicable, include functional derivation, failure-mode analysis, distinction testing, removal testing, absorption testing, missing-function testing, cross-context testing, and examination of interactions and Non-Compensability.

Revision of the invariant Core structure shall not be made solely to accommodate terminology, organizational preferences, reporting formats, technological changes, or requirements that can be addressed through contextualization without changing the determination functions of the Core.

Context Guides and other application-specific bases may be revised independently where the revision does not alter the invariant structure or requirements of this Core.

Such revisions may address, as applicable:

- context-specific Quality Outcome Criteria;
- context-specific Critical Conditions;
- Evidence and Evidence Quality requirements;
- Methodological Resolution;
- Applicable Basis and Reference Layer provisions;
- recipient, purpose, or Context requirements;
- Materiality, Uncertainty, and Traceability provisions;
- Harm, Risk, or Safety information;
- communication requirements;
- Interfaces; and
- other justified application-specific provisions.

A revision at the Context Guide or application level shall not be used to redefine, add, remove, merge, divide, or rename a Core Quality Factor or Quality Indicator in a manner that changes its determination function.

Where application experience indicates a possible limitation in the invariant Core structure, the matter shall be documented and referred to controlled review of the Core rather than resolved through uncontrolled modification at the application level.

Changes in the Applicable Basis, Reference Layer, law, regulation, standard, scientific or professional knowledge, technology, communication systems, or other external conditions shall be evaluated for their effect on applicable Quality Outcome Criteria, Critical Conditions, Evidence requirements, Interfaces, and other application provisions.

Such external change shall not by itself be treated as requiring revision of the invariant Core structure.

Where revision changes the substantive meaning or application of a requirement, the revised provision shall identify or otherwise preserve Traceability to the nature and basis of the change to the extent necessary for responsible use of the Core.

Where a revision affects previously established Context Guides or other applications, the effect of the revision on those documents and applications shall be examined rather than presumed.

A revised Core provision shall not be represented as having governed a prior Quality Determination where that provision was not applicable at the time of that determination, unless the Applicable Basis expressly requires retrospective application.

Similarly, a Quality Determination made under an earlier applicable edition shall not be represented as a determination under a later edition without appropriate review against the later applicable requirements.

Revision shall preserve the distinction between clarification of existing meaning and substantive change in methodological or normative requirements.

Editorial revision shall not be used to introduce a substantive methodological change without identifying that change as such.

Superseded provisions, editions, or application documents shall remain identifiable to the extent necessary to preserve Traceability of Quality Determinations and Quality Claims made under them.

Revision of this Core shall preserve alignment with applicable WQI root concepts and methodological principles, including the distinctions among:

- the Quality State of an original Quality Object and the Quality State of a Quality Claim;
- Evidence and Evidence-Supported Findings;
- Findings and Conclusions;

- substantive Conclusions and Refusal to Express a Conclusion;
- Quality, Harm, Risk, and Safety; and
- invariant Core structure and contextualized application provisions.

Controlled revision shall not presume that the present four Quality Factors and seven Quality Indicators are permanently closed to methodological development.

Any proposed addition, removal, or modification shall, however, require sufficient methodological justification and controlled review before becoming part of the invariant Core.

Controlled revision therefore permits the Quality Claim framework to develop in response to justified methodological and application needs while preserving the stability, distinctions, and Traceability necessary for consistent determination of Claim Quality.

References

The following WQI publications provide the principal methodological and terminological basis for this Core.

1. Whole Quality Institute (WQI). WQI_VOC1 — Whole Quality Root Vocabulary Standard. Revision 2.6, October 2026.

Establishes the controlled WQI terminology and root concepts applicable to this Core, including Quality, Quality Object, Quality State, Intended Function, Intended Result, Quality Factor, Quality Indicator, Quality Outcome Criterion, Evidence, Evidence Quality, Evidence-Supported Finding, Quality Determination, Materiality, Synthesis of Material Findings, Positive Conclusion, Conditionally Positive Conclusion, Negative Conclusion, Refusal to Express a Conclusion, Quality Claim, Traceability, Uncertainty, Critical Condition, Harm, Risk, and Safety.

2. Whole Quality Institute (WQI). WQI_FTA16 — From Quality Conditions to Claims: The Claim as a Quality Object. Foundational Article 16 — First Edition, 2026.

Establishes the methodological basis for forming a Quality Claim from applicable Findings and for treating the Claim as a separate Quality Object with its own Intended Function, Quality State, and Quality Determination.

3. Whole Quality Institute (WQI). WQI_QCJ1 — Research and Justification of Quality Claim Factors and Indicators: Functional Derivation and Cross-Context Testing of a Claim Quality Structure. Article — October 2026.

Provides the research and methodological justification for the four Quality Factors and seven Quality Indicators established by this Core.

4. Whole Quality Institute (WQI). WQI_EQC1 — Evidence Quality Standard — Core. First Edition — September 2026.

Establishes the WQI Core structure for determining Evidence Quality and provides the methodological relationship among Quality Indicators, applicable Quality Outcome Criteria, Evidence, Evidence-Supported Findings, Quality Determination, and Quality State.

5. Whole Quality Institute (WQI). WQI_EQJ1 — Justification of the WQI Core Evidence Quality Factors and Indicators: Cross-Domain Methodological Justification and Comparative Stress Testing of the WQI Evidence Quality Core Architecture. Article — September 2026.

Provides methodological research and justification concerning functional derivation, failure modes, distinction, removal, absorption, missing-function testing, cross-domain testing, interaction, Non-Compensability, Uncertainty, Traceability, and controlled revision used as methodological precedents in development of the Claim Quality structure.

The current applicable edition of a referenced WQI publication shall be used where the Applicable Basis requires use of the current WQI methodological framework.

Where a Quality Claim is applied within a specific domain, jurisdiction, profession, technical system, organizational setting, or other Context, additional references may be established through the applicable Context Guide, Applicable Basis, Reference Layer, or another justified application-specific basis.

Such application-specific references do not become normative references of this Core merely because they are used in a particular application.

Where a referenced source is revised, the effect of that revision on this Core and on an applicable Quality Determination shall be considered in accordance with Section 8, Controlled Revision.

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Document designation: WQI Quality Claim Standard — Core (WQI_QCC1) - October 2026.