



IHTSDO Quality Framework Toolkit

Framework description and example/prototype application

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Version 2.0

Amendment History

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Review Timetable

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Enquiries and advice on use:

For any enquiries and/or advice on the IHTSDO Quality Assurance framework and toolkit, please contact Jane Millar, Chief Quality Officer, IHTSDO, jmi@ihtsdo.org and we welcome feedback

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1 Introduction and document purpose

The purpose of this document is to provide a simplified description of the Quality Assurance Framework along with tools to implement, for use in helping to identify, and subsequently monitor, appropriate and meaningful quality components for the activities and products of the International Health Terminology Standards Development Organization (IHTSDO). This document should be read in conjunction with a more detailed description of the IHTSDO Quality Assurance Framework and how it has been developed – ‘IHTSDO Quality Assurance Framework – introduction and description of IHTSDO quality assurance framework’.

Structurally, the Quality Assurance Framework is a merger of models from the world of software quality engineering, from healthcare quality assurance and existing terminology quality assurance processes, recognising both the wider international harmonization responsibilities of the IHTSDO, as well as the role of its terminology products in healthcare delivery.

This document provides practical guidance to assist in implementation and incorporation of the Quality Framework into current IHTSDO activities and product developments, whether these are the planning or conduct of IHTSDO projects or services. An example of its application with reference to early plans for the IHTSDO ICD-10 mapping project is supplied for illustrative purposes, as well as a suggested format for documenting and sharing the component-characteristic-metric descriptions to increase the chance of their re-use in other projects. Further examples will be developed and shared over time.

2 Framework Summary and Explanation

The IHTSDO quality assurance can be summarized thus:

In order to satisfy its stated purposes the IHTSDO will undertake many project or service activities. By identifying these activities, it is then possible to specify the **components** (depending on their nature these may be ‘structure’, ‘process’ and ‘outcome’ components) that are needed to enable these activities. By identifying suitable **characteristics** by which to assess these components, it will then be possible to measure, demonstrate and improve the quality of each activity the IHTSDO undertakes, by generating **quality metrics**. Each quality metric will consist of one or more **quality targets** against which the **characteristics** of the **components** can be assessed, along with a **plan** or description as to how they will be achieved. The ability to measure the degree of adherence to (or **achievement** of) such targets will then allow the IHTSDO to satisfy itself, its stakeholder and its potential stakeholders of the quality of the activities it performs. If at any stage target levels of quality are not achieved, or if targets are revised, a description of the **response** (such as a change to the planned approach to achieving the target) will be agreed and the metric re-tested.

This summary is illustrated in Figure 1. Although single boxes are shown, any IHTSDO Project or service may be expected to have many ‘quality measurable’ components, each component may have many measurable ‘quality characteristics’ and each characteristic may be measured by several metrics and targets.

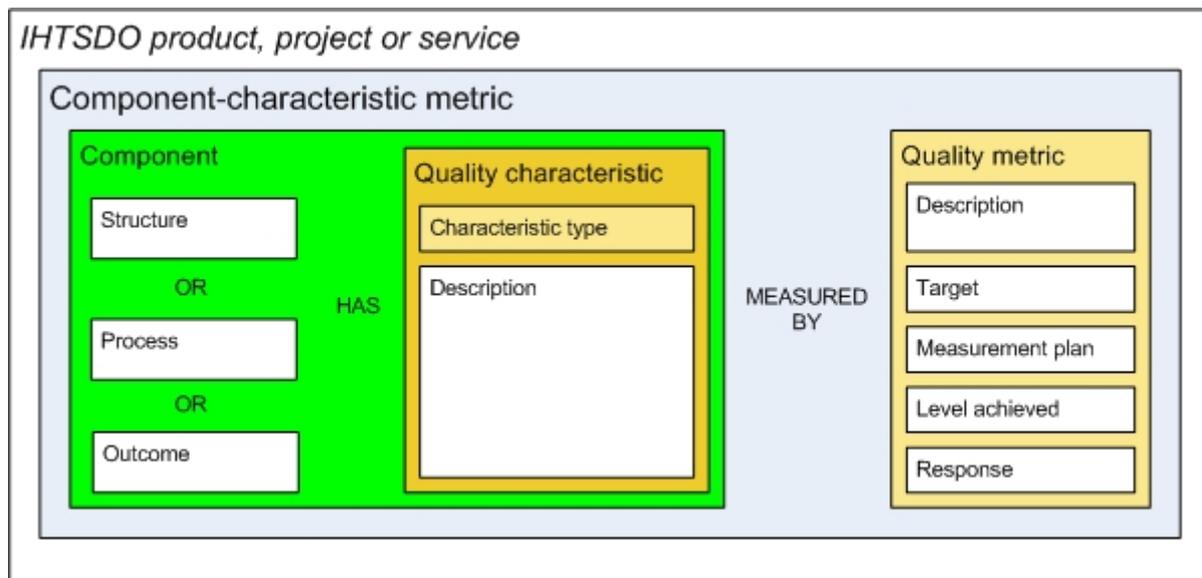


Figure 1: IHTSDO Quality framework summary. See text for explanation

Considering the notions introduced in this summary in a little more detail:

2.1 Component-characteristics

Annex 7 of the IHTSDO Quality Assurance Framework document presents a number of quality characteristics suitable for categorizing quality attributes of various structure, process or outcome components. The most stable and best defined of these are the ‘terminology quality characteristics’ derived from ISO/IEC 9126-1:2001. Nevertheless it should be possible to use any of the characteristic types offered as prompts and cues to identify those ‘component-characteristics’ that are of most importance to the overall quality of the product, project or service under consideration. Casting ahead to the SNOMED CT-ICD 10 mapping example, we see the clause:

A minimum of two MAP editors will independently assess all MAP data records except those with candidate maps. Non-concordant records will be reviewed by the MAP lead in conjunction with a team of editors to resolve conflicting assignments.

Inspecting the available ‘quality characteristics’ set, developers may agree that addressing this clause will cover ‘map set-reliability’ or ‘map set-consistency’ component-characteristic pairings. Once a high-level component-characteristic pairing is agreed, this should be accompanied by a detailed description of the desirability and means of achieving high quality for this pairing.

2.1.1 Components

Components are sub-parts of a product, project or service. Categorizing them as ‘structure’, ‘process’ or ‘outcome’ components is not vital, but may help for subsequent retrieval/reuse or for identification of appropriate characteristic types.

2.1.2 Characteristics

As stated above, the Quality Framework presents a number of quality characteristics suitable for categorizing quality attributes of various structure, process or outcome components. The list provided is still relatively subjective (except for those derived from the software-based ISO/IEC 9126-1:2001, and even these still need localizing for the 'terminology' domain), nevertheless they provide cues for the many dimensions of quality that might need consideration.

2.2 Metrics

Quality Metrics are agreed methods and means for measuring the agreed levels of achievement, performance or conformance of a component-characteristic. They can be expanded into:

- **Description:** A description of what is to be measured and how this is believed to demonstrate the quality of the associated component-characteristic
- **Target:** Quality targets are agreed levels of achievement, performance or conformance of a component-characteristic that would be felt to demonstrate adequate quality.
- **Plan:** A description of how measurement is to be carried out
- **Level achieved:** An agreed reporting format for the metric once measured (units, timescale)
- **Response:** Agreed response steps to follow when this metric is reported (in particular if targets are not achieved) or when a target is revised.

3 Framework application

3.1 General application

3.1.1 Design and development stages

What needs to be done: Agreeing the most appropriate component-characteristic pairings and the most appropriate metrics with which to demonstrate corresponding achieved quality should be an integral component of any project, product or service planning activity.

By whom: Any activity undertaken by the IHTSDO will have a number of stakeholders (broadly divided into suppliers and customers), and consultation between relevant stakeholder groups during project design, product design and service development (or at any review stage) should include the production of a mutually agreed set of component-characteristic pairings and accompanying metrics.

How: Realistically any set will be incomplete – some stages of product development or service delivery will not be measured, and some will only be measured partially or by the evaluation of proxy measures. The intention instead is that given stakeholder expertise (and evolving wider IHTSDO experience), a small set of significant measures (and targets) can be agreed that are (as a reworking of the 'SMART' criteria frequently applied to personal and organizational objectives):

- **Specific:** The agreed component-characteristic pairing should be sufficiently precise to allow subsequent testing and evaluation against targets
- **Meaningful:** The agreed component-characteristic pairing should be interpretable by all stakeholders as a meaningful attribute of the activity under consideration

- **Achievable:** The targets chosen for corresponding metrics should be achievable within anticipated resources and when compared with best estimates/empirical evidence.
- **Realistic:** The agreed component-characteristic (and the planned corresponding metrics) should be possible given anticipated resources, tooling and workflow.
- **Timely:** Corresponding metrics (and the ability to respond when metric results are below targets set) should be available in a timely fashion to all stakeholders.

Each of the above criteria mean that selected metrics may require piloting or testing steps to establish whether the metrics are indeed achievable, realistic etc. – it is expected that such testing requirements will be included in any project or service modification plan.

3.1.2 Conduct stages - measurement

What needs to be done: The project, product or service activity should begin according to agreed processes.

By whom: By those identified as responsible in the metric collection plan.

How: Agreed component-characteristics and corresponding metrics should be collected according to agreed timescales and collection methods (i.e. a metric collection plan and publication schedule (by when and to whom)).

Results should be published according to the agreed timetables, formats and to the agreed recipient lists, with appropriate opportunity for comment.

3.1.3 Post-measurement stages

What needs to be done:

Existing measures: If targets are demonstrably achieved, and if the 'response' section of the metric plan indicates that no further steps are required, then it should be enough to store the record of the metric achievement. Conversely, if targets are not achieved, or if the response plan includes an intention to modify (for example increase stringency) of agreed targets routinely, then such changes should be instituted according to agreed service or project change processes.

Novel measures: It is likely that during the course of any activity, in response to input from any stakeholders, new measures with new perceived benefits will be identified, and their consideration should be encouraged.

By whom: by the agreed responsible individuals for the project or service, including reporting to/communication with project group members and overseeing bodies (e.g. associated SIGs and Committees).

How:

Existing measures: Following the publication of metric results, additional steps as agreed in the 'response' section of the metrics description should be followed, agreed service or project change processes.

Novel measures: These should be considered and developed according to agreed service or project change processes, with due consideration for the resource and productivity implications. Following such change analysis, new metrics may augment or may replace existing metrics.

3.2 Relevance to project work

When applied to IHTSDO project development therefore, the sequence of events will often be:

1. During requirements gathering, elicit and agree with stakeholders which components of project design, project performance or project deliverable will require and will most usefully allow the setting and measurement of quality characteristics. There is little point in setting quality standards that would be impossible or impractical to measure, neither is their point in measuring quality characteristics that are of little known use.
2. For each identified component:
 - agree suitable characteristics
 - agree acceptable targets
 - modify project design in order to measure the agreed component characteristics.
 - Include the regular consideration of quality metrics as part of project conduct, adjusting relevant project components to maintain satisfactory achievement of targets
 - Include quality metrics results with other project deliverables

3.3 Relevance to service work

When applied to IHTSDO service provision or conduct, the sequence of events will often be:

1. Whether identified during internal review or raised by stakeholder comments and feedback, elicit and agree with stakeholders which components of service design, service performance or service deliverable are of concern, and how these can be most usefully allow the setting and measurement of quality characteristics.
2. For each identified component:
 - agree or reappraise suitable characteristics
 - agree or reappraise acceptable targets
 - modify service design in order to measure the agreed component characteristics.
 - reassess relevant quality metrics following service redesign
3. Publish novel metrics results, or continue to publish standing metrics

Example of service metric which is linked to records of the processing of each travel reimbursement form is shown on the next page:

Component	Characteristic and Description		Metric	Target	Result	Owner
Travel Reimbursement Request Forms	Char:	Efficiency	Proportion of travel reimbursement forms that are finalized within 10 working days	100%		SBA
	Descr:	The speed with which travel reimbursement forms are responded to				

4 Example project application

The following worked example (to the point of identifying component characteristics) is provided based on a number of clauses supplied in the ‘quality assurance plan’ of the IHTSDO SNOMED CT to ICD-10 cross mapping project. At this stage it illustrates the design and development stages for a limited number of clauses. As the actual project progresses it is expected that both the number of clauses explored, and the depth of the examples (into later project stages) will increase and this document can be revised. Note that for initial versions of this document the detail provided in the examples is illustrative, and not agreed by/committed to by the relevant project groups.

Sample clauses/sub clauses (full wording in Annex 1):

- Editorial consistency:
 1. Statistical profiling of SNOMED CT core content will be accomplished to assure that all neoplastic disorders characterized by the associated morphology codes of ICD-O version 3 are present in the disorders hierarchy.
 2. A minimum of two MAP editors will independently assess all MAP data records except those with candidate maps.
 3. Non-concordant records will be reviewed by the MAP lead in conjunction with a team of editors to resolve conflicting assignments.
 4. Heuristics and assumptions will be updated in this documentation as exceptions are resolved.
 5. Map blocks not meeting statistical criteria will be resubmitted to the map process after revision of documentation and training.

It is assumed that all these clauses are targeted toward the accurate and consistent production of SNOMED CT to ICD-10 cross maps. The opening sections are therefore either:

- ***Project, product or service name** – Mapping SNOMED CT to ICD-10 project
- ***Responsible owner** – xxxxxxxxxxxxxxxxxxxxxx
- ***Component name** – Editorial consistency of maps

or

- ...
- ***Component name** – Accuracy of maps

Then, taking each clause/sub clause in turn, a set of component-characteristic pairings and corresponding metrics might be:

1. Statistical profiling of SNOMED CT core content will be accomplished to assure that all neoplastic disorders characterized by the associated morphology codes of ICD-O version 3 are present in the disorders hierarchy.

Component	Characteristic and Description		Metric	Target	Result	Owner
Editorial consistency of maps - structure Completeness of maps	Char:	Comprehensiveness	completeness of ICD-O/disorder matching (20080807)	100%		
	Descr:	all morphology codes from ICD-O version 3 should have corresponding neoplastic disorder codes in the disorders hierarchy – such a feature is important to allow consistent map creation, and to allow consistent guidance for record entry creation.	The number of ICD-O morphology codes that have an agreed corresponding disorder code.			

2. A minimum of two MAP editors will independently assess all MAP data records except those with candidate maps.

Component	Characteristic and Description		Metric	Target	Result	Owner
Accuracy of maps - Process Reproducibility of Maps	Char:	Reliability	independent assessor map concordance (20080807)	100%		
	Descr:	This will provide evidence of the number of the degree of consistency/concordance between independent map editors using agreed heuristics	A measure of the number of concordant maps achieved by independent map editors			

These clauses represent part of a 'measurement plan' or 'planned response if target not achieved' for a 'Reproducibility of maps' component characteristic measure (e.g. clause 2). If a target of 100% mapping concordance was set, then '3' represents the activity undertaken when non-concordance occurs (further expert review), and '4' represents a later activity undertaken where expert review reveals improved or additional heuristics. '5' refers to 'statistical criteria – these can be thought of as the metric 'targets'.

5 Interim approach to component-characteristic-metric register

The Quality Framework recommends that a database of component-characteristic-metric sets be developed for the IHTSDO to allow for reuse and sharing of quality metric activities between and within IHTSDO groups. In the absence of a dedicated database to serve this function, it is proposed that, as an interim measure, any groups that develop Quality Framework-conformant metrics are encouraged to record them in the standard template. This will at least allow simple textual searching of one another's quality metrics work, and ultimately would allow the same data to be entered into a more sophisticated index and search environment.

Suggested fields for recording each component-characteristic-metric are as follows (“*” indicates mandatory fields):

- ***Project, product or service name** – this will allow cross-referencing to identify
- ***Responsible owner** – this is the name of the project, product or service lead
- ***Component name** – this may be the whole name of the project, product or service, or may be a component/part of the
 - **Component type** – structure, process or outcome
- ***Quality characteristic name** – short working name for the thing being measured (probably most easily framed as “characteristic’ of ‘component’” (such as “accuracy of SCT-ICD-10 cross maps”)
 - **Quality characteristic type** – the characteristic category from the Quality Framework
 - **Quality characteristic description** – a description and justification for the characteristic
- ***Quality metric name** – short working name for the metric (there may be several metrics for each quality characteristic, so these will need to be distinguished)
 - ***Date of agreement**
 - ***Description** – a description and justification for the metric
 - ***Target** – the target to be achieved.
 - ***Measurement plan** – a description of
 - how the metric will be generated and collected
 - by whom
 - timing in relation to project/service
 - publication schedule
 - review timetable
 - ***Planned response if target not achieved**
- Outcomes would not routinely form part of a metric register, but fields to collect would be:
- ***Outcome**
 - ***Date of measure**
 - ***Level achieved** – the measure achieved
 - ***Remedial/additional steps taken** - if required

6 Annex 1 – Original text of SCT-ICD Quality assurance plan

Quality assurance plan:

- Editorial consistency: Statistical profiling of SNOMED CT core content will be accomplished to assure that all neoplastic disorders characterized by the associated morphology codes of ICD-O version 3 are present in the disorders hierarchy.
- The mapping staff will be managed and work coordinated by a MAP lead. The MAP lead will prepare an education plan for editors, reviewers and validators and be responsible and accountable that all participants have been trained in procedures and metrics.
- The MAP lead will employ the tool set to efficiently queue and manage mapping work load, beginning with the priority core set identified by the IHTSDO members and proceeding as the management board assigns. Source code sets for mapping will be organized into reasonable units of work (blocks) for each map editor.
- A minimum of two MAP editors will independently assess all MAP data records except those with candidate maps. Non-concordant records will be reviewed by the MAP lead in conjunction with a team of editors to resolve conflicting assignments. Heuristics and assumptions will be updated in this documentation as exceptions are resolved. Map blocks not meeting statistical criteria will be resubmitted to the map process after revision of documentation and training.
- Internal review of the MAP will occur incrementally, at least quarterly, and concurrently by IHTSDO members and WHO designees.
- Map blocks released from editorial review will be accompanied by concordance statistics. The IHTSDO and WHO will designate staff for review of MAP statistics and a further sampling of MAP data records for study early in the formative process. Internal review staff will employ the same mapping tools. Statistics will be maintained on their editorial assignments. Inter-rater concordance rates by editorial staff and internal reviewers will be published for map documentation
- External review agencies will be chosen by IHTSDO members and WHO. External validators which will participate in training and the formative development of the MAP. External review will employ the same tools and procedures as that on internal review. Statistical concordance will meet the same requirements.
- Operative validation:
 - IHTSDO and WHO will establish a network of operative testing sites at the outset of the project

Anonymized test sets will be developed and distributed to testing sites. A Gold standard MAP will be developed by the lead editor and staff. Mapped records submitted from the testing sites and compared to the Gold standard. Concordance will meet statistical requirements as identified above.