



IHTSDO Quality Assurance Framework

Introduction and description of IHTSDO quality assurance
framework

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Version 2.0

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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 background to development

The purpose of this document is to provide a description of the Quality Assurance Framework 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 separate toolkit document which gives further examples and templates which can be used i.e. implementation guidance – ‘IHTSDO Quality Framework Toolkit’

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, recognizing both the wider international harmonization responsibilities of the IHTSDO, as well as the role of its terminology products in healthcare delivery.

The principles which underpin the original development of the IHTSDO Quality Assurance Framework are:

In order to satisfy its stated **purposes** the IHTSDO will undertake many **activities**. By identifying these activities, it is then possible to specify the **components** (themselves identifiable in terms of ‘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** and setting **quality targets** against which the **characteristics** of the **components** can be assessed. The ability to measure the degree of adherence to (or achievement of) such targets will then allow the IHTSDO to satisfy itself, its stakeholders and its potential stakeholders of the quality of the activities it performs (be they, for example, service provision, data publication or internal organizational conduct).

By example:

The IHTSDO states that one of its purposes is to ‘...promote and enable the uptake and correct use of its Terminology Products in health systems...’ Amongst the many activities required to achieve this stated purpose will be ensuring the provision of call centre services to manage customer inquiries. From a quality assurance perspective, ‘call centre service provision’ can then be represented in terms of a number of components e.g. a ‘structure’ component such as the number of call centre staff, a ‘process’ component such as the way a particular licensing inquiry from an affiliate is dealt with (including clear documentation of the currently agreed way to respond to the inquiry), or an ‘outcome’ component such as the suitability of the response from the perspective of the affiliate customer.

Taking just one of these components (e.g. a 'process' component), it will then be possible to view it in terms of various quality characteristics or dimensions. We may, for example, select two competing process characteristics such as 'adaptability' and 'standardization', and assess the extent to which various licensing inquiries have been dealt with – whether similar inquiries are handled in a 'standardized' way, and whether idiosyncratic inquiries are handled in an acceptable and adaptable fashion. Where concerns are identified, the IHTSDO will then have a framework in place for analyzing where remedial steps can be made and making the necessary changes (e.g. simply revising aspects of process, or looking to modify structural components such as staff numbers, training and competencies).

The anticipated benefits of having this Quality Assurance Framework agreed and in place is to support a consistent, systematic and ubiquitous approach to the incorporation of quality assurance practices into any IHTSDO activities. Whether manifesting as surveys or studies to identify priority areas for quality improvement, the specification and introduction of novel quality assurance practices to an established or newly introduced activity, or the documentation and presentation of established quality assurance activities, an agreed quality assurance framework will allow this to be done in a consistent, comparable and systematic way.

This document itself is organized in the following way:

- **Introduction**
- **Definitions** are offered to clarify further the document's scope and provide consistent reference for later sections.
- The framework itself is first introduced in **Quality Framework and application within IHTSDO**
- **Annex A ('Examples of IHTSDO activities and quality framework components')**. A detailed description is found in section 4 of the use of a template and section 5 provides a more generic approach to projects and services (**components, characteristics, metrics and improved activities**).
- **Annex B** summarizes the Quality Assurance Committee's discussions on novel quality characteristics that could be used with a framework for definitions which will be added as further work progresses both on the use of the framework and introducing an IHTSDO glossary.

2 Definitions

The following working definitions are offered to support later sections of this document. They are a merger of reworked IEEE software definitions, ISO terminology definitions and a reframing of some of the more fundamental descriptions of the IHTSDO into the form of definitions. The rationale is to build up to the combined IHTSDO and Terminology Quality Assurance Framework definition found in section 2.7 and to keep all aspects of IHTSDO activity in scope for Quality Assurance scrutiny.

2.1 International Health Terminology Standards Development Organization

Abbreviation: IHTSDO

Definition:

The organization that is responsible for owning and administering the rights to SNOMED CT, other health terminologies and/or related standards, as well as being responsible for the development, maintenance, promotion and enablement of the uptake and correct use of its Terminology Products in health systems, services and products around the world.

2.2 IHTSDO Quality

Definition:

The degree to which the IHTSDO meets its specified objectives, in terms of its organizational and product development processes, as well as the services and products it provides.

2.3 IHTSDO Quality Assurance

Abbreviation: IHTSDO QA

Definition:

A planned and systematic pattern of actions necessary to provide confidence that the IHTSDO meets its specified objectives, in terms of its organizational and product development processes, as well as the services and products it provides.

2.4 Terminology

Context: Health

Definition:

A structured, human and machine-readable representation of clinical concepts required directly or indirectly to describe health conditions and healthcare activities, and allow their subsequent retrieval or analysis. Also *the relationship of the terminology to the specifications for organizing, communicating and interoperating such a set of concepts*¹.

Source: adapted from ISO 17115:2007

¹ Note: Given other ISO 17115:2007 definitions that accompany 'clinical terminology' and 'reference terminology', the scope of definition 2.4 includes mappings to classifications, as well as including description translations to various languages and dialects.

Comment: the use of the term terminology in healthcare implies a terminology that is designed for use in computer systems.

2.5 Terminology Quality

Definition:

The degree to which a terminology, component or process meets mutually agreed customer and organizational requirements and satisfies stated IHTSDO purposes.

2.6 Terminology Quality Assurance

Abbreviation: Terminology QA

Definition:

A planned and systematic pattern of actions necessary to provide confidence that the terminology and its development and maintenance processes conform to mutually agreed customer and organizational requirements and satisfy stated IHTSDO purposes.

2.7 IHTSDO and Terminology Quality Assurance Framework

Definition:

The Components required to support and make accessible for review the planned and systematic pattern of actions necessary to provide confidence that the

- terminology and associated products
- organisational and product development processes
- associated IHTSDO services
- and the performance of the IHTSDO

conform to mutually agreed customer and organizational requirements and satisfy stated IHTSDO purposes.

2.8 Component

Definition:

Components are sub-parts of a product, process or service. Components can be categorized as structural, process or outcome that can be quantified or measured (and as such can be modified), in order to improve the quality of IHTSDO activities and products. They might be people, technical infrastructure/tooling artefacts, documented processes and procedures, as well as the product and service outputs of the IHTSDO.

Guide for use:

Rather than assigning quality measures to projects or services directly, the identification of the Components of a project or service allows more precise Characteristics to be identified, more specific descriptions of those Characteristics as applied to each Component, the setting of meaningful quality targets and the collection of credible Quality Metrics.

2.9 Quality Characteristics

Definition:

A typology of attributes of an IHTSDO Component by which its quality is assessed or measured. A typology is the study or systematic classification of types that have attributes or traits in common.

2.10 Quality Target

Definition:

Quality targets are agreed levels of achievement, performance or conformance of a Component for any given Quality Characteristic.

2.11 Quality Metric

Definition:

Quality Metrics are agreed methods and means for measuring the agreed levels of achievement, performance or conformance of a component or its quality characteristic(s).

3 Quality Framework and Application within IHTSDO

As stated in the introduction, the approach taken in this framework description is based on the following principles:

- IHTSDO objectives and purposes are the motivating principles for IHTSDO activities, and
- IHTSDO activities act as the organizing principle for quality framework components

3.1 IHTSDO objectives and purposes are the motivating principles for IHTSDO activities

It should be possible to trace back all IHTSDO activities to one or more stated purposes or objectives in the IHTSDO Articles. These are as follows (from the June 2007 Articles of the Association):

3.1.1 Purposes of the Association

- (a) to acquire, own and administer the rights to SNOMED CT, other health terminologies and/or related standards, and other relevant assets (collectively, the "Terminology Products");
- (b) to develop, maintain, promote and enable the uptake and correct use of its Terminology Products in health systems, services and products around the world; and
- (c) to undertake any or all activities incidental and conducive to achieving the Purpose of the Association

3.1.2 Objectives of the Association

- (a) enhance the health of humankind by facilitating better health information management
- (b) to contribute to improved delivery of care by clinical and social care professions;
- (c) to facilitate the accurate sharing of clinical and related health information, and the semantic interoperability of health records;
- (d) to encourage global collaboration and cooperation with respect to the ongoing improvement of the Terminology Products; and
- (e) to provide the foregoing on a globally co-ordinated basis, thereby enabling the Members and the related organizations within their Territories to pool resources and share benefits relating to the development and maintenance of, and their utilization of and reliance upon, the Terminology Products.

All activities should be seen to satisfy or address a number of purposes or objectives (so restating them here may seem unnecessary), however if it is possible to identify IHTSDO activities that do not appear to correspond with any of the purposes, then their appropriateness should be questioned. It should be noted, however, that some activities, whilst not addressing purposes and objectives stated in the Articles, are fundamental to the workings of the IHTSDO itself.

3.2 IHTSDO activities act as the organizing principle for quality framework components

The purposes and objectives summarized above guide the activities of the IHTSDO.

Using the diagram below as an illustration along with Annex A :

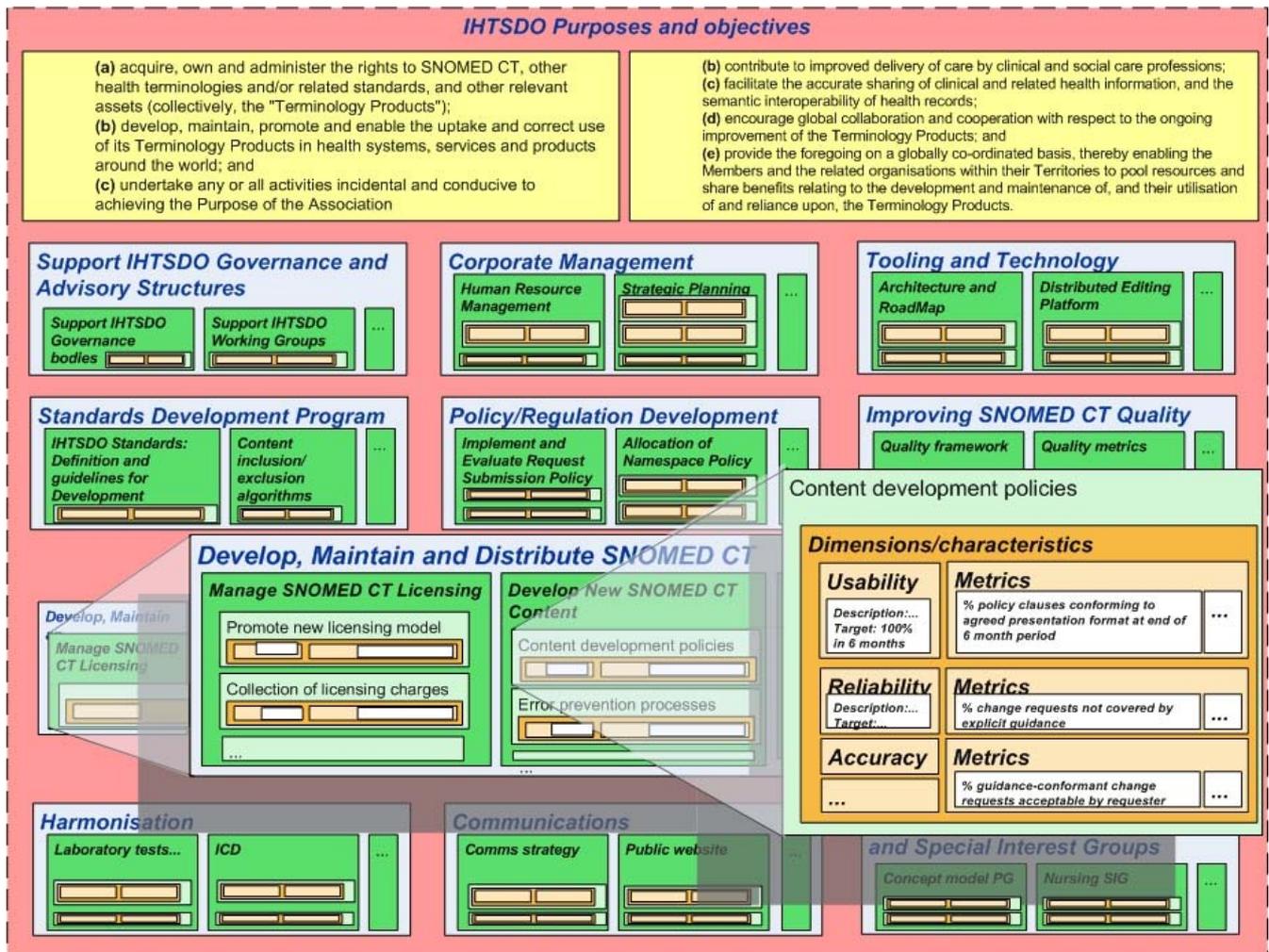


Figure 1: Schematic decomposition of IHTSDO activities to sub-activities, quality framework components, relevant quality characteristics and associated measures and targets.

The purposes and objectives of the IHTSDO (yellow boxes on pink background) motivate all IHTSDO activities (top-level categorization in blue boxes). Activities can generally be thought of as programmes of work.

IHTSDO activities are further decomposed into sub-activities (dark green boxes). Sub-activities generally can be thought of as projects and services. Analysis of sub-activities will reveal components (pale green boxes) that may represent:

- structure (e.g. staffing levels or tooling capabilities)
- process (e.g. workflow policies and descriptions) or
- outcome (e.g. published documents and data)

Components will therefore have a close relationship to the elicited requirements for any project or service, and as a first step those responsible for each project or service should be able to satisfy themselves (and any other IHTSDO stakeholders) that the relevant components exist in some form for each activity undertaken. The next ('quality') stages are to identify the quality characteristics (orange and nested pale orange boxes) for each component, and ultimately set targets or standards for such characteristics, take measurements (metrics), and publish achievement figures. Where targets are identified and the ability to demonstrate target achievement does not yet exist; products and processes will need to be revised and augmented to allow such measures to be made. Where achievement and performance fall short of targets, the components or the targets themselves can then be appropriately revised and the target/measurement processes repeated.

The example magnified activity is to 'develop, maintain and distribute SNOMED CT'. This activity can be decomposed into sub-activities such as 'manage SNOMED CT licensing' and 'develop new SNOMED CT content'. In order to undertake this latter sub-activity, a number of components are needed. Two that are shown are 'content development policies' and 'error prevention processes'. 'Content development policies' are further magnified to illustrate how appropriate quality 'characteristics' can now be associated with this component. In this example characteristics such as 'usability', 'reliability' and 'accuracy' (a non-exhaustive set, hence the ellipsis) are identified as being relevant characteristics of 'content development policies'. More focused descriptions of each characteristic, along with target levels of quality achievement, can then be agreed. In this case a meaningful statement of 'usability' might refer to the benefits of a consistent way of presenting content development guidance. Relevant parties could then agree a target – for example that within 6 months 100% of content development guidance clauses would have a 'unique short name', a justification, a longer narrative description and come with at least three examples. Publishing technologies and processes could be reviewed to allow the generation of metrics and, at the end of the 6 month time frame, a measure of achievement could be produced. Such a measure would then be made available to all relevant stakeholders. Any achievement shortfall would prompt an appropriate review, resulting in agreed changes to the target or the component and a repeat of the cycle.

It is reasonable to assume that for some components and characteristics measures are more significant than others, and that components are not independent. In the example above it may be that despite the non-achievement of 100% in the 'development policy consistency' metric, it was still possible to demonstrate a high achievement in content development consistency and accuracy. It might then be reasonable to accept that good quality data was being produced despite inconsistencies in development policy layout, with consequent relaxation in the target.

3.3 Quality Ownership

By its purposes and objectives, the IHTSDO is undertaking many activities, each with many associated structure/process/outcome components - and each of these, in turn, with many associated quality characteristics, metrics and targets. Ultimate responsibility operationally for IHTSDO quality will sit with the Management Board, and responsibility for maximally delivering IHTSDO quality within resources sits with the Chief Executive and Executive Officers. The General Assembly may expect quality reporting against strategic objectives and targets and will therefore maintain an overview.

It would be inappropriate for direct day-to-day responsibility for all quality activities to fall to one small group of individuals or one committee. It is therefore expected that, consistent with the current IHTSDO work plan publication, direct responsibility for the day-to-day identification of quality components, targets and metrics for each identified project or service sits with the named project or activity lead, with candidate quality targets and metrics proposals being an expected component of any project or service description, and outlined in the project descriptions that are used to define new work items. This way any targets and metrics approaches can be agreed with stakeholders during the appropriate phases of project description and development.

Where there is debate with regard to suitable, appropriate or achievable targets, or where identified quality characteristics will have a costly or disruptive impact on current or anticipated processes, these should be escalated (in order) to the following individuals or groups for advice and resolution:

- The Chief Quality Officer
- The IHTSDO Quality Assurance Committee
- The Chief Executive Officer
- The Management Board

As introduced in Annex A (**Examples IHTSDO activities and quality framework components**), a consistent approach to representing IHTSDO quality activities will allow the collation and indexing of established component/characteristic/target and metric sets, and consequently allow them to be searched and reused in novel but comparable projects and services.

3.3.1 Quality Assurance Framework Scope

As indicated above, it is the intention that the quality assurance framework will cover all identifiable aspects of IHTSDO activity, including:

- Organisational processes and support
- Data products (terminology reference data, mappings, translations, subsets)
- Documentation
- IHTSDO-responsible services and tooling provision.

It would be expected that localisation activities (subset development, content extensions) could adopt a similar and comparable framework, but specific targets, metrics and methodologies may vary between settings. It cannot be assumed that all quality processes will be automatically appropriate for all settings, however where differences occur these should be clearly stated, and, where relevant, any necessary remedial steps to move towards more stringent standards should be indicated.

4 Framework Description

4.1 Overview

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 maintain or, as necessary, 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 2. 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.

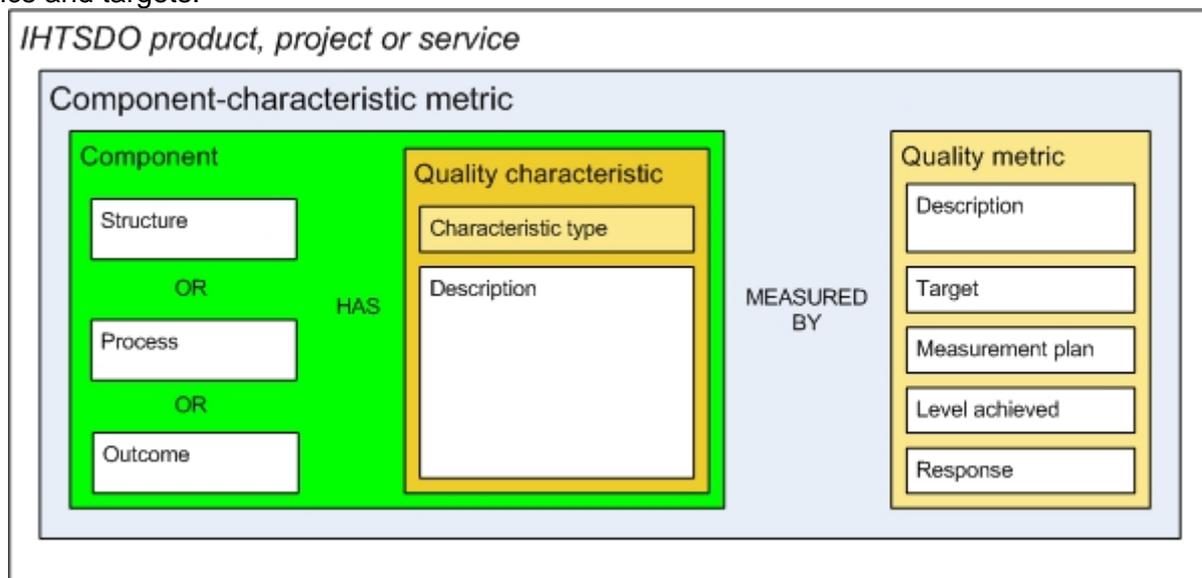


Figure 2: IHTSDO Quality framework summary. See text for explanation

4.2 Component-characteristics

Annex 7 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.

4.2.1 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.

4.2.2 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.

4.3 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.

5 Applying the Quality Framework

5.1 Projects and services

There is a requirement to set targets and demonstrate meaningful quality standards for all IHTSDO projects and services, at any stage in their development and conduct – see scope section 3.3.1. The IHTSDO quality framework will not, of itself, say what these standards are, but will provide a consistent mechanism for identifying project or service components, specifying the quality characteristics/attributes of each component, setting standards or targets for each characteristic, and identifying a realistic mechanism for measuring (and demonstrating) whether such standards are achieved.

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 and achievably allow the setting and measurement of quality characteristics. This latter point ('useful and achievable') is included to emphasise that there is little point in setting quality standards that would be impossible or impractical to measure, neither is there 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

An example is found in 6.1.4.1.

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 most usefully and achievably 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
 - publish novel metrics results, or continue to publish standing metrics

An example is found in 6.1.1.1.

Not all component quality characteristics will yield simple-to-agree quality targets and measurement methods and in some situation quality characteristics may stand in conflict, e.g. stability and flexibility. Agreeing 'optimal' content development approaches or content distribution approaches will depend on

many different variables, and setting ‘targets of perfection’ in standards for content quality must be balanced with what is achievable within known resources and processes at any point in time². Nevertheless a combination of the Quality Framework as an organising structure for approaching quality issues, along with the growing experience of IHTSDO members, staff and expert committee members should allow a consistent, open and incremental mechanism for agreeing and setting quality standards, providing clear information (and managing expectation) of all relevant stakeholders.

5.2 Quality characteristics

Quality characteristics can be thought of as properties of each quality framework component. A detailed and validated set of characteristics is yet to be produced for the precise purposes of the IHTSDO, but a candidate set of ‘characteristic’ words (along with some localizable definitions) has already been reused from the software quality assurance industry, healthcare quality assurance and from the October 2007 IHTSDO QAC meeting in Copenhagen. Some are presented in **Annex B**.

Over time a rationalization process will be performed, and agreed (industry appropriate) definitions will be developed for the accepted quality characteristics. This will ultimately allow a more systematic development of suitable quality assurance metrics.

5.3 Components, characteristics, metrics and improved activities

The real value in developing a quality framework model is the ability to sustain or improve the quality of IHTSDO activities (whether goods or services) by the development, collection and analysis of quality metrics.

By the combination of quality components (be they based on structure, process or outcome) and appropriate characteristics, it should be possible to assess current practice, set realistic goals or levels of quality and measure whether these are achieved. Ultimately it should be possible to develop sensible targets and metrics for any IHTSDO activity.

² For example, any measures of terminology ‘completeness’ or ‘accuracy’ for the whole of SNOMED CT are unrealistic – measuring and demonstrating achievement would require comparison with an error-free and complete alternative that does not exist. It is more realistic to set standards with regard to the speed, efficiency, and expert panel resource availability for managing sporadic change requests. By contrast, discrete new content development or existing content refinement projects can be scaled and performed in such a way that ‘completeness’ and ‘accuracy’ *can* be assessed against clearly-specified editorial ideals and clearly-stated content requirements.

6 Annex A

6.1 Examples of IHTSDO activities and quality framework components

The IHTSDO activities used are structured according to the high level chapter headings in the IHTSDO's Work Plan. These sections, along with a brief purpose description and example sub-activities and relevant framework components are reproduced below. The intention of this section is to indicate how a systematic analysis of IHTSDO activities will reveal the detailed tasks that it has committed to perform (or ensure are performed), and subsequently reveal the structure/process and outcome 'framework components' suitable for measurement and standards setting. The intention is that a database of established component/characteristic/target and metric sets can be collated and indexed, allowing their inspection for assessment of IHTSDO quality, as well as their reuse and tailoring for novel issues of quality improvement. The use of such a database should not stifle the careful introduction of innovative quality assessments where these are felt to be superior or more appropriate.

In addition to the Quality Framework examples, the sections entitled **Develop, Maintain and Distribute SNOMED CT** and **Improving SNOMED CT quality** also describe a number of 'strategic' prerequisites that will complement a framework approach to content development and improvement.

6.1.1 Support IHTSDO Governance and Advisory Structures

Program Purpose:

These activities include facilitating meetings and providing secretariat services to the General Assembly, Management Board, Standing Committees and Working Groups as outlined in the Articles of Association

Example sub-activities, components, characteristics and metrics:

6.1.1.1 Providing assistance to IHTSDO standing committees

The IHTSDO must be able to provide (and demonstrate provision of) services and clear processes for the election, formation and running of IHTSDO standing committees (including provision of secretariat services and a collaborative workspace). Illustrative component, characteristic, metric and target sets are shown in Table 1 on the next page:

Component	Characteristic and Description		Example target	Metric
Committee running processes	Char:	Efficiency	100% in 5 working days	Proportion of committee meeting minutes posted to collaborative space by 5 working day UTC deadline after each meeting.
	Descr:	The speed with which first draft minutes are produced		
Committee running structure	Char:	Reliability	100%	Number of announced meetings that take place at the date/time originally agreed.
	Descr:	The ability to adhere to originally-stated meeting plans.		

Table 1: illustrative IHTSDO standing committees' quality framework sets

6.1.2 Corporate Management

Program Purpose:

These are activities performed to ensure a sustainable and robust organization capable of responding to stakeholder requirements.

Example sub-activities, components, characteristics and metrics:

6.1.2.1 Development of a staffing and recruitment plan

The IHTSDO must be able to advance and maintain a well-staffed office to support all relevant activities. This will include accurate and timely staff level estimates, and timely recruitment. Illustrative component, characteristic, metric and target sets are shown in Table 2:

Component	Characteristic and Description		Example target	Metric
Recruitment process	Char:	Responsiveness	100%	Number of new posts filled in 7 months of a decision to recruit.
	Descr:	The ability to meet internal recruitment deadlines		
Recruitment outcome	Char:	Effectiveness	*	* Hard to measure objectively, but in principle an 'organisational quality' issue
	Descr:	The ability to recruit staff with appropriate competencies		

Table 2: illustrative 'staffing and recruitment plan' quality framework sets

6.1.3 Develop, Maintain and Distribute SNOMED CT

Program Purpose:

These are activities performed to ensure the continued development, maintenance, distribution and correct uptake of SNOMED CT.

Example sub-activities, components, characteristics and metrics:

6.1.3.1 Manage SNOMED CT Licensing

The intention for this piece of work is to ensure that the new licensing model for SNOMED CT is implemented and managed, and that all appropriate licence charges are collected. Recruitment Illustrative component, characteristic, metric and target sets are shown in Table 3:

Component	Characteristic and Description		Example target	Metric
Licence charge collection	Char:	Effectiveness	100%	Number of known revenue-generating affiliate license fees collected by due date
	Descr:	To ensure that all known license fees are collected		

Table 3: illustrative 'Manage SNOMED CT Licensing' quality framework sets

Complementary to the example 'framework-based' decomposition of known IHTSDO SNOMED CT quality improvement activities, the following strategic notes are provided.

Terminology content development

6.1.3.2 Quality components of the terminology content development lifecycle

As a specific extension to general project management (and also including a number of terminology 'service' components) this section would generally include:

- Policies for content development (e.g. editorial guidance materials, as well as processes for their updating, testing and dissemination)
- Training schedules and desirable/essential employee attributes for those staff with editing access to the SNOMED CT terminology reference data.
- Based on realistic productivity estimates (given various terminology team configurations and ways of working), policies for adequate staffing levels.

More specifically it would include:

Change request and requirements gathering mechanisms

- Agreed policies for content requirements gathering (to be sympathetic with the project management techniques mentioned above).
- Published policies for change request management (e.g. editorial issues resolution, request turnaround expectations)

- Evidence of suitable tooling to support the above

Error prevention/detection mechanisms and infrastructure

- Agreed policies for content error detection and prevention (e.g. editorial guidelines – that are themselves demonstrably reproducible).
- Policies for carrying out the editorial guidelines described above when manipulating the reference data (including minimum expectations for human/machine contributions to this effort)
- Performance and operational characteristics (e.g. server redundancy) of technical infrastructure
- Processes (and evidence of suitable tooling) for supporting adherence to the rules above, including adequate staffing levels

Testing mechanisms

Policies and processes for ‘adequate’ content testing. This would include auditable minimal testing steps that should be applied to all new/existing content. There may also be additional testing steps that could be applied to specific content (e.g. ‘*this* content for *this* use in *this* setting’) that might allow an even greater level of testing assurance.

6.1.4 Standards Development Program

Program Purpose:

These are activities performed to provide the principles and processes to which Members and Affiliates must conform when further developing the terminology and its related standards.

Example sub-activities, components, characteristics and metrics:

6.1.4.1 Standard for Translation of SNOMED CT

Through the application of best practice and implementation experience, this piece of work will allow efficient and continuously improving translation efforts. Illustrative component, characteristic, metric and Target sets are shown in Table 4:

Component	Characteristic and Description		Example target	Metric
Translation conduct process	Char:	Portability	100%	Number of translation projects that produce summary reports of costing and lessons learned.
	Descr:	The ability for each translation exercise to learn from previous translations		
Translation data outcomes	Char:	Functionality	*	* Number of automated description translations that can faithfully be interpreted when analysed in a ‘translated to’ language. Likely to require specific
	Descr:	The ability for each ‘completed’ translation to allow meaningful cross-language/cross-dialect translation in test		

		implementations		studies and consideration of know best outcomes when setting targets.
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Table 4: illustrative 'Standard for Translation' quality framework sets

6.1.5 Policy/Regulation Development

Program Purpose:

These are activities that allow the rapid development of policies to guide operational processes. There are two types of policies and regulations – external and internal. External policies and regulations govern how the IHTSDO does business with its Affiliates, National Release Centres and Support organisation. Internal policies and regulations govern how the IHTSDO will conduct its own affairs.

Example sub-activities, components, characteristics and metrics:

6.1.5.1 International release process

This activity includes the release process itself, including clear definitions of the content and its availability mechanisms and timetables. Illustrative component, characteristic, metric and target sets are shown in Table 5:

Component	Characteristic and Description		Example target	Metric
International data release outcome	Char:	Understandability	100%	Proportion of files published that correspond to previously agreed/trailed file manifest.
	Descr:	Faithfulness of published files, file structures and naming conventions to previously published file manifest		
International data release process	Char:	Reliability	100%	For the data published, amount available in the way, and by the date previously agreed/trailed.
	Descr:	Ability to make data available how and when expected.		

Table 5: illustrative 'International release process' quality framework sets

6.1.6 Improving SNOMED CT Quality

Program Purpose:

These are activities performed to ensure the quality and safety of the content of SNOMED CT, specifically to develop a strategy for the systematic review and improvement of the quality of SNOMED CT and associated IHTSDO activities.

Example sub-activities, components, characteristics and metrics:

6.1.6.1 Incident response service

This piece of work is to expand and clarify the incident report service. Illustrative component, characteristic, metric and target sets are shown in Table 6:

Component	Characteristic and Description		Example target	Metric
Incident response structure	Char:	Appropriateness	*	* Ultimately evidence of 24 hour cover for incident response reporting and response initiation. Anything less than this cover will require clear instructions for management of incidents out of 'cover time'.
	Descr:	The IHTSDO will have sufficient skilled resource available globally to record reported incidents and initiate appropriate remedial steps		
Incident response outcome	Char:	Reliability	100%	With appropriate follow-up analysis, acceptability testing of responses given against timely and safety criteria.
	Descr:	The provision of acceptable, timely and safe responses to reported incidents		

Table 6: illustrative 'Incident response' quality framework sets

Complementary to the example 'framework-based' decomposition of known IHTSDO SNOMED CT quality improvement activities, the following strategic notes are provided.

Quality systems development

Over-and-above the 'general' (IHTSDO-wide) project management framework components for content development, there will be components that would apply to the IHTSDO in its entirety. These would include the quality aspects of organizational structure and process, including a risk management perspective:

- The committees and individual roles (and stated responsibilities) that would be needed for the smooth running of quality assurance within the IHTSDO. These would include the Quality Assurance Committee itself, the Chief Quality Assurance Officer, and might also include minimum standards for similar roles in National Release Centers, as well as additional committees/groups if needed.
- Standards for internal reporting (summary metrics) to the Management Board
- Internal or external audit programmes
- The selection of, and steps to acquire, an appropriate quality standards certification plan

6.1.7 Tooling and Technology

Program Purpose:

These are activities performed to ensure an adequate technical platform for IHTSDO activities. This relates to a number of areas such as content development and collaborative space development – as processes mature it is likely that these activities will converge.

Example sub-activities, components, characteristics and metrics:

6.1.7.1 Request Submission Technical Solution

This project is charged with the documentation of the requirements and solution options for a technical solution to support current and future business needs for terminology change request submissions. Illustrative component, characteristic, metric and target sets are shown in Table 7:

Component	Characteristic and Description		Example target	Metric
Technical solution function/structure	Char:	Reliability	99.99%	Request submission availability using standard system availability measures
	Descr:	Request submission system availability time		
Technical solution process	Char:	Efficient	*	Probably a simple 'does/doesn't' against stated requirement, but may be possible to identify the proportion of requests that cannot be coerced into standard workflow.
	Descr:	System able to support editor workflow practices		

Table 7: illustrative 'Request Submission Technical Solution' quality framework sets

6.1.8 Harmonization

Program Purpose:

These are activities performed to ensure a coordinated and consistent position with other standards development organizations where overlap in requirements/solution space activity is identified. Mechanisms for liaison and harmonization need to be developed where required.

Example sub-activities, components, characteristics and metrics:

6.1.8.1 HL7/ CEN and Information Models

This work involves the production of a board position statement for IHTSDO liaison HL7 CEN and other standards development organisations developing messaging and information models. Illustrative component, characteristic, metric and target sets are shown in Table 8:

Component	Characteristic and Description		Example target	Metric
Position statement development	Char:	Practical/implementable	*	Perhaps difficult to measure in any conventional sense, however it might be possible to scrutinise any position statements produced for 'number of position statement clauses that are
	Descr:	Implementability of relevant position statements		

				practical/implementable'.
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Table 8: illustrative HL7/ CEN and Information Models' quality framework set

6.1.9 Communications

Program Purpose:

These are activities performed to ensure communication with all relevant stakeholders. Such activities include the maintenance of websites and collaborative spaces, liaison with Members and Affiliates and the creation of an Affiliate Forum.

Example sub-activities, components, characteristics and metrics:

6.1.9.1 Liaison with National Release Centers

The purpose of this project is to ensure close liaison between the IHTSDO and the National Release Centres and to leverage the work of the National Release Centres internationally. Illustrative component, characteristic, metric and target sets are shown in Table 9:

Component	Characteristic and Description		Example target	Metric
Education materials (structure)	Char:	Understandability	*	Precise scoring would depend upon assessment techniques used, but Understandability attributes of education materials could be elicited by structured questionnaires.
	Descr:	The extent to which education materials are found to be understandable by their NRC target audiences		

Table 9: illustrative 'Liaison with National Release Centres' quality framework sets

6.1.10 Working Groups and Special Interest Groups

Program Purpose:

These are activities performed to facilitate meetings of Special Interest Groups and Project Groups to support work within the IHTSDO work plan.

Example sub-activities, components, characteristics and metrics:

There are so many working group projects and special interest groups underway that examples may not be helpful. Suffice it to say, as explained earlier, it should be possible to apply the framework steps to the project design stages (in particular eliciting stakeholder-acceptable quality criteria during requirements gathering), incorporate these into project designs and ultimately include published quality measures as project end-project deliverables, as input into milestone progress decision points, or as standing quality measures where projects become services or enter maintenance phases.

7 Annex B: Extended quality characteristics development

Below is a set of what is seen as extended IHTDSO quality responsibilities, example activities and characteristic types. The major headings (Process, Services and Organizational performance) and the associated characteristics are intended to augment the more data-centric 'Terminology' characteristics harvested from ISO/IEC 9126-1:2001 - 'software quality characteristics'. It has been recognized that definitions need to be added to be developed for these characteristics and this has been reinforced with early testing. The definitions are currently being developed, taking into account existing international definitions.

7.1 Process activities

7.1.1 Examples

Methodologies

- Project management
- Balloting
- Governance

7.1.2 Characteristics

Efficiency	
Clarity	
Adaptability	
Usable	
Transparency	
Equitability (fairness)	
Practical/implementable	
Elegant	
Agile	
Standardized	
Non-redundant	
Aligned with articles of association	
Sensitivity - Culturally appropriate	
Sensitivity- Legally acceptable	
Sensitivity - Ethical	

7.2 Service-based activities

7.2.1 Examples

- Education (Education - supported by the curriculum and conformance criteria, and including 'implementation education')
- Training
- Call centre activity
- Release, dissemination

7.2.2 Characteristics (definitions will be introduced for next version)

Functional	
Reliable	
Accessibility and portability	
Responsiveness	
Transportable	
Timeliness	
Improvable	
Comprehensiveness	
Affordability/sustainability	
Consistent	
Understandability	
Appropriateness	
Maintainable	
Usable	
Efficient	

7.3 Organizational performance

7.3.1 Examples

- Stakeholder engagement
- Communication/PR
- Resource provision and management
- Relationship management
- Financial/delivery against planning
- Business development (new members)
- Customer satisfaction

7.3.2 Characteristics (definitions will be introduced for next version)

Attractiveness	
Probity/prudence	
Reliability	
Sustainability	
Effectiveness (in particular around relationship management)	

Trustworthiness	
Responsiveness	
Transparency	
Accountability	
Openness	

7.4 Terminology quality characteristics

These are taken from ISO/IEC 9126-1:2001 - 'software quality characteristics', and would be most directly relevant to included here to allow comparison with the characteristics

- **Functionality** - A set of attributes that bear on the existence of a set of functions and their specified properties. The functions are those that satisfy stated or implied needs.
- **Reliability** - A set of attributes that bear on the capability of software to maintain its level of performance under stated conditions for a stated period of time.
- **Usability** - A set of attributes that bear on the effort needed for use, and on the individual assessment of such use, by a stated or implied set of users
- **Efficiency** - A set of attributes that bear on the relationship between the level of performance of the software and the amount of resources used, under stated conditions.
- **Maintainability** - A set of attributes that bear on the effort needed to make specified modifications.
- **Portability** - A set of attributes that bear on the ability of software to be transferred from one environment to another.

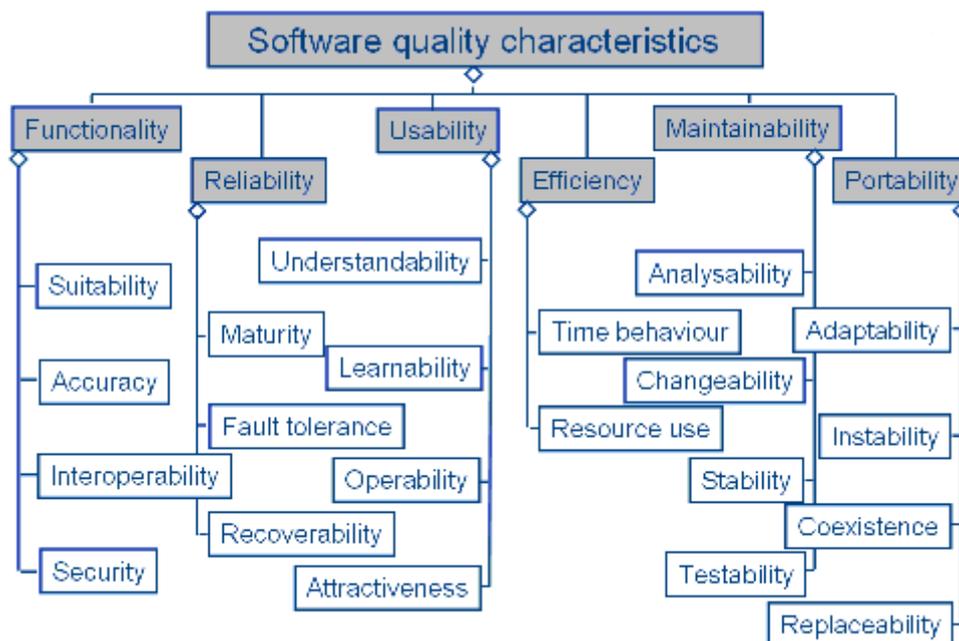


Figure 3: ISO/IEC 9126-1:2001 software quality characteristics (showing detailed sub characteristics)