



**Clinical Terminology  
Guidance for People and Processes v1.0**

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# Document information

## Key information

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# 1 Introduction

## 1.1 Purpose

This document provides guidance for those involved in adopting Australian Medicines Terminology (AMT) v2 or greater or the Systematized Nomenclature of Medicine, Clinical Terms<sup>®</sup> – Australian Release (SNOMED CT-AU)<sup>1</sup>. This guidance may be used to minimise clinical safety risks and maximise the benefits associated with using AMT or SNOMED CT-AU (referred to as 'terminology' in this document).

## 1.2 Intended audience

The intended audience is any entity that adopts terminology, including:

- healthcare software vendors;
- vendors of proprietary terminology products; and
- health jurisdictions and healthcare providers.

## 1.3 Scope

This document is applicable to those organisations involved in the adoption of terminology for use in an Australian context. This document deals with the use of terminology as a native interface terminology and terminology mapping.

The guidance in this document specifically deal with the business processes, documentation and personnel needed to enable mapping, accessing, recording, storing and displaying terminology in a healthcare software system in a manner that reduces clinical safety risks and maximises the business benefits of adopting terminology.

The intent of this document is not to provide specific details or guidelines on software design, terminology reference set selection, custom subset and intentional constraints development, terminology binding, terminology integration, terminology mapping, or verification and testing of terminology in the healthcare software system. Rather, the aim is to provide a set of requirements that emphasise key issues associated with the above-mentioned areas, and which can be used to guide an appropriate terminology adoption approach.

Organisations seeking assistance should consult other guidance such as the *Australian Medicines Terminology v2 Model Mapping Guidelines* [NEHTA2012b], the *SNOMED CT-AU Mapping Guidelines* [NEHTA2014j], the *SNOMED CT Technical Implementation Guide* [IHTSDO2014a] and the *AMT Technical Implementation Guide (v3 model)* [NEHTA2013]. Any additional support can be requested from the National Clinical Terminology and Information Service (NCTIS) via email ([help@nehta.gov.au](mailto:help@nehta.gov.au)).

## 1.4 Compliance

An organisation may want to claim to have implemented this clinical terminology guidance. For such claims to be meaningful and for the healthcare community to have a shared understanding of these claims, the clinical terminology guidance has

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<sup>1</sup> IHTSDO®, SNOMED® and SNOMED CT® are registered trademarks of the IHTSDO.

been documented in the form of requirements using the standard verbs **shall**, **shall not**, **should**, **should not** and **may**. An organisation wanting to claim it has implemented the clinical terminology guidance in this document must meet all mandatory and applicable conditional requirements for those use cases that apply. These are the requirements using the verbs **shall** and **shall not**.

## 1.5 Terminology adoption

The approach to terminology adoption may be different from one organisation to another, depending on the intent and the scope of each implementation. Table 1 identifies a number of use cases related to terminology adoption.

Note that this document uses the generic word *terminology* to refer to AMT and SNOMED CT-AU. Words such as *concept*, *concept identifier*, *description* and *preferred term* are used in the specific clinical terminological sense, unless otherwise specified. See page 69 for a list of terms and their meanings.

Table 1: Terminology adoption use cases

UC ID	Use case
UC.001	Organisation uses terminology release files, customised reference sets, custom subsets and intentional constraints as the basis for developing terminology maps
UC.002	Organisation develops a healthcare software system, allowing the use of terminology through mapping
UC.003	Organisation develops a healthcare software system, allowing the exchange of clinical information in messages or CDA clinical documents using terminology mapping. The organisation may or may not supply terminology as part of software releases
UC.004	Organisation integrates terminology maps into a healthcare software system
UC.005	Organisation uses terminology release files, customises reference sets, or creates custom subsets, intentional constraints or customised terminology descriptions for use as a native interface terminology
UC.006	Organisation develops a healthcare software system allowing the use of terminology as a native interface terminology. The organisation may or may not supply terminology as part of software releases
UC.007	Organisation develops a healthcare software system, allowing the exchange of clinical information in messages or CDA clinical documents using native interface terminology
UC.008	Organisation integrates terminology into the healthcare software system as a native interface terminology
UC.009	The delivery of healthcare is supported by the use of terminology either as a native interface terminology or through terminology maps in the healthcare software system

Where one or more use cases apply to an organisation, the organisation should assess their adherence to the guidance in this document.

Table 2 outlines the different terminology adoption scenarios and provides traceability between the above-mentioned use cases and mandatory sections in this document.

*Table 2: Scenarios, use cases and requirements traceability*

<b>Scenario</b>	Adopting terminology for use in the GUI (native interface terminology)	
	<b>Use Cases</b>	<b>Mandatory sections</b>
	UC.005, UC.006, UC.007, UC.008, UC.009	Section 2
	UC.005, UC.006, UC.007	Section 3
	UC.008	Section 5
	UC.009	Section 6
<b>Scenario</b>	Adopting terminology through mapping (terminology mapping)	
	<b>Use Cases</b>	<b>Mandatory sections</b>
	UC.001, UC.002, UC.003, UC.004, UC.009	Section 2
	UC.001, UC.002, UC.003	Section 4
	UC.004	Section 5
	UC.009	Section 6
<b>Scenario</b>	Adopting terminology through native interface terminology implementation and terminology mapping	
	<b>Use Cases</b>	<b>Mandatory sections</b>
	UC.001, UC.002, UC.003, UC.004, UC.005, UC.006, UC.007, UC.008, UC.009	Section 2
	UC.005, UC.006, UC.007	Section 3
	UC.001, UC.002, UC.003	Section 4
	UC.004, UC.008	Section 5
	UC.009	Section 6

If an organisation wants to claim that they have adhered to the guidance in a section in this document, the requirements listed as mandatory must be supported by the organisation. Conditional requirements are treated as mandatory, provided the condition stated in the requirement is satisfied. Recommended requirements are optional, but are strongly encouraged for organisations to adhere to.

## 1.6 Background

The AMT delivers standardised identification of brand (trade) products and equivalent generic medicines with associated components that are supported through standard naming conventions that accurately describe medications [NEHTA2014f].

SNOMED CT is considered to be the most comprehensive, multilingual clinical healthcare terminology. When implemented in software, SNOMED CT represents clinically relevant information consistently, reliably and comprehensively as an integral part of the electronic health record. SNOMED CT-AU is the Australian extension to SNOMED CT and includes the international resources with all Australian developed terminology and documentation for implementation in Australian clinical information technology systems [NEHTA2014d].

A healthcare provider or vendor may implement AMT or SNOMED CT-AU (or both) in their healthcare software system as a native interface terminology or by mapping a local or proprietary coding system to AMT or SNOMED CT-AU. Mapping allows adoption of terminology for eHealth messaging while preserving the existing local or proprietary coding system. Mapping may also be undertaken to convert existing data records in a different coding system to terminology as part of implementing terminology as a native interface terminology within a healthcare software system.

Terminology contributes to the improvement of healthcare through supporting the recording, display and exchange of healthcare information and the ability to deliver decision support services to healthcare providers. Healthcare consumers benefit from the use of terminology to more clearly describe and accurately record their healthcare information. Other benefits include:

- Terminology provides clinical efficiency and a consistent vocabulary across all healthcare domains.
- Terminology reduces error rates and promotes recording of clinical information at the required level of granularity.
- Terminology enables the consistent retrieval, exchange and analysis of recorded clinical information.
- The consistent use of terminology reduces the risk of incorrect interpretation of clinical information.
- Terminology supports semantic interoperability.
- Terminology promotes reusability (e.g. record once, use many times).
- Terminology enables consistent representation of clinical terms.
- Terminology enables machine processing of clinical information.
- Terminology allows extensibility through a controlled approach to further enhance its usability and coverage.

These benefits are major drivers for organisations to adopt terminology. However, to support the realisation of these benefits, those working to develop, integrate and maintain terminology within a healthcare software system require a comprehensive understanding of the ontology. This is not insignificant given the amount and, at times, complex nature of the information that needs to be understood. Areas of coverage include, but are not limited to, file formats, terminology components,

relationship types, hierarchies, reference sets and the interaction between the terminology and the information model.

Unfortunately, having an indepth understanding of terminology is only a small part of terminology adoption. Organisations require various groups of skilled professionals from different backgrounds and knowledge domains to support the adoption process. However, even with a highly competent workforce, state-of-the-art technology, and documentation and support services available to an organisation, there are still clinical safety and business risks that may be introduced during the adoption process and ongoing use. A national approach is therefore needed for the Australian healthcare landscape to ensure that risks associated with terminology adoption are adequately and consistently managed.

This may be achieved by adherence to the guidance in this document, ensuring consistent use of terminology to allow healthcare providers to communicate effectively and accurately across clinical domains, and to address differences in information exchange models that could hinder interoperability. Organisations, including healthcare providers, adhering to this guidance will have improved confidence in the business processes they follow and healthcare software systems they develop and use.

The guidance in this document includes rules for policies, business processes, practices, use of tools and people that are based on industry best practices and standards, including guidelines by prominent bodies such as the International Health Terminology Standards Development organisation (IHTSDO) and NCTIS, NEHTA.

The clinical terminology guidance for people and processes offers a number of advantages. These are:

- Mitigation of risks.
- Assists in dealing with the complexities of terminology implementations and use.
- Mitigation of risks that are, in many cases, considered preferred alternatives to more expensive or inappropriate workarounds using software requirements.
- Introducing consistent adoption approaches across the Australian healthcare industry.

In addition to the guidance in this document, a number of other guidelines and supporting documentation have been developed to mitigate clinical safety risks and maximise the benefits of adopting terminology. Please refer to *Table 3* for more details.

## 1.7 Related documents

Table 3 lists related terminology documents.

Table 3: Related documents

Document title	Description
1 <i>Clinical Terminology – Guidance for Use in Healthcare Software</i> [NEHTA2014h]	Describes guidance for use of AMT and SNOMED CT-AU in healthcare software.
2 <i>Clinical Terminology – Tests for Use in Healthcare Software</i> [NEHTA2014a]	Describes test cases for testing adherence to the guidance for use of AMT and SNOMED CT-AU in healthcare software.
3 <i>Clinical Terminology – Guidance for Use of Medical Nomenclatures in Information Exchange</i> [NEHTA2014i]	Describes guidance for the use of medical nomenclatures in clinical messages and CDA documents.
4 <i>Clinical Terminology – Tests for Use of Medical Nomenclatures in Information Exchange</i> [NEHTA2014c]	Describes the test cases for testing adherence to the guidance for use of medical nomenclatures in clinical messages and CDA documents.
5 <i>AMT Mapping Guidelines</i> [NEHTA2012b]	Describes a mapping methodology for mapping local and proprietary coding systems to AMT.
6 <i>SNOMED CT-AU Mapping Guidelines</i> [NEHTA2014j]	Describes a mapping methodology for mapping local and proprietary coding systems to SNOMED CT-AU.
7 <i>Australian National Terminology Release Licence Agreement</i> [NEHTA2009]	Details terms that licence holder must comply with.
8 <i>SNOMED CT Affiliate License Agreement</i> [IHTSDO2009]	Details terms that licence holder must comply with.

## 1.8 Development of clinical terminology guidance

This guidance has been derived from:

- Licence agreements[IHTSDO2009], implementation and user guides for the SNOMED CT International Release by the IHTSDO and [IHTSDO2014a];
- SNOMED CT-AU resources published by the NCTIS [NEHTA2014j] , [NEHTA2014d], and [NEHTA2014e];
- AMT resources published by the NCTIS [NEHTA2009], [NEHTA2011a], [NEHTA2012a], [NEHTA2012b], [NEHTA2012c], [NEHTA2013], [NEHTA2014e], [NEHTA2014f]; and
- Clinical safety risks assessments.

## 2 Licence requirements

All parties who download and use SNOMED CT-AU release files must agree to the *SNOMED CT Affiliate Licence Agreement* [IHTSDO2009] and the *Australian National Terminology Release Licence Agreement* [NEHTA2009].

All parties who download and use AMT release files must agree to the *Australian National Terminology Release Licence Agreement* [NEHTA2009].

Requirements apply to an organisation, within the context of relevant use cases. Requirements listed as mandatory must be met by the organisation. Conditional requirements are treated as mandatory, provided the condition stated in the requirement is satisfied. Recommended requirements are optional, but strongly encouraged.

### **021566 SNOMED CT licence holder**

If SNOMED CT-AU is in use, the terms stated in the *SNOMED CT® Affiliate Licence Agreement* and the *Australian National Terminology Release Licence Agreement* **shall** be adhered to.

**Priority** Conditional

**Applicable to** UC.001, UC.002, UC.003, UC.004, UC.005, UC.006, UC.007, UC.008, UC.009

#### **Additional Notes**

The licence agreement and the national terminology release are made available by NEHTA. The licence holders may grant sub-licences to the users of the licensee healthcare software system. This is a licensee obligation. [NEHTA2009 and IHTSDO2009]

### **021567 AMT licence holder**

If AMT is in use, the terms stated in the *Australian National Terminology Release Licence Agreement* **shall** be adhered to.

**Priority** Conditional

**Applicable to** UC.001, UC.002, UC.003, UC.004, UC.005, UC.006, UC.007, UC.008, UC.009

#### **Additional Notes**

The licence agreement and the national terminology release are made available by NEHTA. The licence holders may grant sub-licences to the users of the licensee healthcare software system. This is a licensee obligation. [NEHTA2009]

## 3 Requirements for native interface terminology

The requirements in this section apply to an organisation developing healthcare software systems that support the use of terminology as a native interface terminology. The organisation may either supply terminology with the software release, or enable users to customise, integrate and maintain terminology in the healthcare software system.

If the organisation does not release and maintain terminology data with its software, the organisation should raise awareness of these requirements among their users.

Requirements apply to an organisation, within the context of relevant use cases. Requirements listed as mandatory must be met by the organisation. Conditional requirements are treated as mandatory, provided the condition stated in the requirement is satisfied. Recommended requirements are optional, but strongly encouraged.

### 3.1 Purpose and scope

#### **021570** Defining a native interface terminology adoption strategy

A strategy outlining the purpose and scope of terminology adoption as a native interface terminology, including the type of clinical information to be captured and presented in the healthcare software system **shall** be clearly defined, documented and shared with those required to make informed and definitive decisions in relation to:

- the design, development and testing of the healthcare software system;
- the inclusion or exclusion of terminology reference sets;
- the development of custom subsets and intentional constraints;
- the process of terminology binding; and
- the integration, validation and testing of terminology in the healthcare software system.

Where the purpose or scope has changed, the documentation **shall** be updated accordingly.

**Priority** Mandatory

**Applicable to** UC.005

## **021570 Defining a native interface terminology adoption strategy**

### **Additional Notes**

A strategy statement is needed to direct the adoption and use of terminology. It serves as a reminder of the overall direction of the adoption and ongoing use of terminology and directs the development of value domains that are exact, relevant and fit for use.

There are numerous options for adopting terminology. Specific implementation or customisation decisions can only be made if the purpose and scope has been clearly defined. The statement needs to include details of what objectives terminology needs to fulfil, and to what extent. A well-developed statement informs, directs and constrains development of value domains and increases the chances of delivering an output that is clinically safe and relevant.

Answering the following questions allows a starting point for those developing the purpose and scope statement:

- Why is the terminology being considered for use?
- How will terminology be used:
  - Will terminology be used to represent clinical information in patient records?
  - Will terminology be used to enable knowledge representation (e.g. electronic reference books, clinical guidelines, care pathways, decision support protocols)?
  - Will terminology be used for aggregation and analysis purposes (e.g. data warehousing)?
  - Will terminology be used as a service to enable end user implementation to access terminology through a terminology server or browser?
  - Will terminology be used to exchange clinical information?
- What type of data will be involved to record, store, display or exchange using terminology (e.g. diagnoses and problems, procedures history, administrative information)?

Refer to chapter 3 of the *SNOMED CT Technical Implementation Guide* [IHTSDO2014a] for additional details that may be considered when writing the purpose and scope statement.

The scope and purpose statement needs to be written and verified by the personnel who possess the required competencies (refer to requirement 021582).

**021571 Purpose and scope of information model artefacts**

The purpose and scope of each element in the healthcare software system's information model subject to terminology binding **shall** be documented and shared with those required to make informed and definitive decisions in relation to:

- the inclusion or exclusion of terminology reference sets;
- the development of custom subsets and intentional constraints;
- the process of terminology binding; and
- the integration, validation and testing of terminology in the healthcare software system.

Where changes to the information model or healthcare software system are made, the documentation **shall** be updated accordingly.

**Priority** Mandatory

**Applicable to** UC.005

**Additional Notes**

The intent of this requirement is to allow the development of value domains that are accurate, complete, and fit for use. Clearly defined scope and purpose statements of each element in the information model supports the development and integration of value domains and the verification and testing of developed value domains, including the ongoing maintenance of terminology in the healthcare software system.

Answering the following questions allows a starting point for those developing the purpose and scope statements:

- Why is this data field required?
- Why is this data field exposing terminology?
- How will the terminology-enabled data field be used:
  - Will the data field be used to display clinical information?
  - Will the data field used to record clinical information?
  - Will the data field enable display or recording of post-coordinated expressions?
- What is the context of the data field:
  - What is the type of administrative or clinical data to be accessed through the data field?
  - Is there a change of meaning of terminology content by the context?

The scope and purpose statements need to be developed and verified by the personnel that possess the required competencies (refer to requirement 021582).

**021572            Constraining terminology content according to defined purpose and scope**

The development of value domains (i.e. selection of terminology reference sets, development of custom subsets, intentional constraints, customised terminology descriptions (CTDs) and locally defined concepts (LDCs)) **shall** be in line with the terminology strategy statement and **shall** be consistent with the documented purpose and scope of associated information model elements during the binding process (i.e. terminology binding).

**Priority**            Mandatory

**Applicable to**    UC.005

**Additional Notes**

The intent of this requirement is to reduce the risk of allowing invalid terminology concepts to be recorded in a terminology-enabled data field and to increase the possibility in finding the correct terminology concept.

A set of terminology concepts (i.e. value domain), made available through a terminology-enabled data field during the integration process, is only made possible through the documented relationship of the value domain and a particular information model element. For this reason, it is important to document the purpose and scope of each information model element and the associated value domain.

It is acceptable to allow access to one or more reference sets within a single terminology or across multiple, whichever addresses the need. For example, a terminology-enabled data field intended to record substance or agents causing adverse reactions in patients may constrain access to both the SNOMED CT-AU *Adverse Reaction Agent* reference set and the AMT *Trade Product Pack* reference set.

With appropriately designed data fields and appropriately constrained terminology data, terminology data integrators can limit the risk of clinical users not being able to find the most appropriate terminology concepts to express clinical statements. Not limiting such a risk may result in the clinical user selecting an inferior or incorrect concept to express a clinical statement. It is therefore important that those responsible for designing the software and those responsible for constraining and integrating terminology data into the healthcare software system work closely to ensure the correct balance between logical software designs and appropriate aggregation of terminology data.

A systematic and carefully planned approach in selecting terminology references sets and refining and developing customs subsets, intentional constraints and CTDs is, therefore, needed by the organisation responsible for the manipulation, refinement and integration of terminology data into the healthcare software system. The healthcare software system must be tested for clinical correctness, clinical safety and quality, end to end across all workflows, once implemented in the healthcare software system for each release or revision.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility to meet this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021570, 021571, 021580

**021581 Inclusion or exclusion criteria for value domains**

The criteria used to determine the terminology concepts, CTDs and LDCs to be included or excluded from each value domain **shall** be clearly defined and documented. The documentation **shall** be maintained in accordance with changes made to the value domains or the healthcare software system. The rationale for any changes **shall** also be documented.

**Priority** Mandatory

**Applicable to** UC.005

**Additional Notes**

The organisation or user is to fully analyse and document how terminology concepts are identified for inclusion or exclusion in the custom subset or through the application of intentional constraints. Without a set of clearly defined criteria, inconsistent decisions could be made to include or exclude terminology concepts in the healthcare software system.

The inclusion or exclusion criteria of value domains need to be developed by personnel who possess the required competencies and who are involved in the development of value domains (refer to requirement 021582).

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021586 Purpose and scope of CTDs and LDCs**

If CTDs or LDCs are to be developed, the purpose and the scope of each CTD or LDC **shall** be documented and **shall** align with the purpose and scope of the value domains they belong to. Traceability between CTD and LDC and the value domains **shall** be documented. The documentation **shall** be maintained in accordance with changes made to the CTDs and LDCs, value domains, or the healthcare software system. The rationale for any changes **shall** also be documented.

**Priority** Conditional

**Applicable to** UC.005

**Additional Notes**

The intent of this requirement is to allow those developing CTDs or LDCs to consider why it is needed and where it will be used. Having a clearly documented purpose and scope supports ongoing maintenance of CTD or LDC in the context of other terminology concepts for a particular value domain and terminology binding.

The scope and purpose statements need to be developed and verified by personnel who possess the required competencies (refer to requirement 021582).

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021571, 021572

**021580      Maintaining traceability between value domains and the information model**

All terminology bindings **shall** be documented. The documentation **shall** be maintained in accordance with changes made to the value domains or the healthcare software system and the information model. The rationale for any changes **shall** also be documented.

**Priority**            Mandatory

**Applicable to**    UC.005

**Additional Notes**

The intent of this requirement is to support the development, integration and ongoing maintenance of value domains in the healthcare software system and to ensure it is done in a manner that would not introduce clinical safety risks.

Consistent representation is a prerequisite for effective retrieval and reuse of clinical record information [IHSDO2014a]. Since both the information model and terminology contribute to the meaning of clinical statements recorded and displayed in the healthcare software system, it is critical that these interdependencies are documented and managed appropriately. Having this documented also assists in the verification of value domains in relation to the information model and assists in identifying errors or limitations at both ends.

The development and maintenance of the documentation need to be conducted by personnel with required competencies who are involved in the development of value domains (refer to requirement 021582).

Where the organisation allows the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021572

## 3.2 Quality assurance

### 021583 Ensuring the development of value domains meet acceptable quality standards

The process of developing value domains **shall** incorporate quality controls, and **shall** be supported by local policies and business processes.

**Priority** Mandatory

**Applicable to** UC.005

#### Additional Notes

Developing custom subsets, intentional constraints, CTDs or LDCs with no quality controls may produce an output that is not fit for use and may introduce clinical safety risks. Those responsible for overseeing the adoption of terminology need to ensure that local policies and business processes that mandate quality controls are in place.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021588, 021633

**021588 Suggested quality controls for the development of value domains**

The process of developing value domains **should**, as a minimum, incorporate the following quality controls:

- Ensure the development process was followed and the production and update of appropriate documentation was undertaken.
- Ensure developed value domains and their association with the information model was correctly defined and maintained.
- Ensure fully specified names (FSNs) were used as a basis for developing CTDs.
- Ensure developed CTDs are correct and unambiguous representations of the associated terminology concepts.
- Ensure terminology reference sets were used as a foundation for the development of custom subsets, where appropriate.
- Ensure the introduction of synonymous concepts within value domains were avoided.
- Ensure those involved in the development process possess required competencies.
- Ensure user documentation is adequate and accompanied with the healthcare software release.
- Ensure peer reviews were undertaken.
- Ensure acceptance and signoff by relevant stakeholders and clinical users.

**Priority** Recommended

**Applicable to** UC.005

**Additional Notes**

Developing value domains with no quality controls may not produce an output that is clinically safe and fit for use.

Those responsible for the development need to understand that this requirement only identifies a limited set of recommended quality controls, and that additional quality controls are needed that best align with organisational policies, adopted or internally developed standards and procedures.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021583, 021633

## 3.3 Development practices

### 021573 Collaboration between developers and terminology integrators

Those responsible for designing and developing the healthcare software system, developing value domains, undertaking terminology binding, and constraining and integrating terminology data into the healthcare software system **should** work closely together to ensure the correct balance is struck between logical/usable software designs and appropriate aggregation of terminology data for each terminology-enabled data field.

**Priority** Recommended

**Applicable to** UC.005, UC.006, UC.007

#### Additional Notes

The intent of this requirement is to limit the risk of users recording clinical statements that are ambiguous or erroneous, as a result of poorly constrained terminology content. The information model and the healthcare software system design may have an impact on the ability for terminology to be effectively constrained. Therefore a systematic and carefully planned approach is needed during the design of the software and the development of value domains, so that the combination of the two will result in a usable, effective and clinically safe product.

### 021584 Subset of NCTIS published content

A subset should be developed from a NCTIS published terminology reference set where the reference set meets the defined intent of the custom subset.

**Priority** Recommended

**Applicable to** UC.005

#### Additional Notes

The NCTIS has developed a range of terminology reference sets for various applications. It is suggested that these reference sets be used as a starting point when developing custom subsets. This may include using some or all of the reference set content together with additional content as required for creating a local or custom subset. Where the content within the custom subset differs from the nationally released reference set, the subset must bear a different name to the national reference set. For example, if there is a need to develop a custom subset containing only those procedures that may be used in a gastroenterology unit, the *Procedure Foundation* reference set should be used as a starting point for further customisation of the SNOMED CT-AU content.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

### **021590 Using the FSN as the basis for developing a CTD**

If CTDs are to be developed, the creation of each CTD **shall** be based on the associated terminology concept's fully specified name (FSN) which provides an unambiguous representation of the terminology concept. The FSN **shall** be an active description for that terminology concept.

**Priority** Conditional

**Applicable to** UC.005

#### **Additional Notes**

The intent of this requirement is to ensure that CTDs are not based on terminology synonyms as it may result in deviating from the true meaning of the terminology concept.

The creation of CTDs should be carefully considered. It is strongly suggested that if an organisation wished to develop CTDs, the NCTIS is contacted for advice and support.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

### **021620 Specificity of CTDs**

If a CTD is to be developed, the CTD **shall not** be more specific than the terminology concept's FSN.

**Priority** Conditional

**Applicable to** UC.005

#### **Additional Notes**

The intent of this requirement is to ensure that CTDs accurately represent the terminology concept. CTD must not be developed and used if it is found that a CTD is more specific than the terminology concept's FSN with. For example:

- FSN: "Removal of device (procedure)";
- CTD: "Removal of prosthetic device".

If existing CTDs are found to fall under this category, the CTDs have to be made inactive and labelled as ambiguous [IHTSDO2014b].

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021632 Broader CTDs**

If a CTD is to be developed, the CTD **shall not** be more general than the associated terminology concept's FSN, unless the CTD, in conjunction with the context in which the CTD will be used, presents the same meaning as the FSN.

**Priority** Conditional

**Applicable to** UC.005

**Additional Notes**

The intent of this requirement is to ensure that CTDs accurately represent the terminology concept it will be associated with. A CTD must not be used if it is found the CTD is more general than the terminology concept's FSN with no context to convey an accurate representation of the terminology concept. For example:

- FSN: "Sprain (morphologic abnormality)";
- CTD: "Joint injury".

If existing CTDs are found to fall under this category, the CTDs have to be made inactive and labelled ambiguous [IHTSDO2014b].

However, a more general CTD is considered valid when there is a context where the more general CTD has the same meaning as the FSN. For example:

- FSN: "Entire fundus uteri (body structure)";
- CTD: "Fundus", in the context of obstetrics.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021593      Avoiding synonymous concepts when creating LDCs or CTDs**

If LDCs or CTDs are to be developed, each value domain which will include the newly created LDCs and CTDs **shall** be analysed in order to limit or prevent synonymous descriptions from being introduced during the process.

**Priority**                      Conditional

**Applicable to**      UC.005

**Additional Notes**

The intent of this requirement is to reduce the risk of recording incorrect clinical statements that may be used in making clinical decisions regarding a person's healthcare.

The term 'synonymous' in the context of this requirement refers to descriptions with the same text, independent of case and punctuation. It also refers to descriptions with similar or the same meaning, look-alike or sound-alike. For example:

- 'myocardial infarction' and 'heart attack', or
- 'fit' meaning a state of being healthy and 'fit' meaning a seizure.

When there is a need to create an LDC or CTD for a particular value domain, those responsible for creating such localised content must consider the implications it will have on clinical safety and usability. The introduction of an LDC or CTD should not be synonymous with other descriptions in the same value domain where it will be used. Where synonymous descriptions are exposed through a particular terminology-enabled data field, the healthcare software system must be able to identify such concepts to the user and provide additional information about the concepts, to enable the clinical user to differentiate [NEHTA2014h].

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 3.4 Personnel

### **021633 Personnel involved in defining quality controls supporting development of subsets, intentional constraints, CTDs and LDCs**

Those personnel involved in defining the quality controls and supporting business processes around the development of value domains **shall** possess quality assurance, clinical knowledge and an understanding of healthcare software system information model.

**Priority** Mandatory

**Applicable to** UC.005

#### **Additional Notes**

The intent of this requirement is to ensure that those with sufficient experience and skills are involved in defining quality controls that, in turn, are to be used to ensure that the development of terminology subsets and intentional constraints, CTDs and LDCs are at an acceptable level of quality. With quality assurance in place, those using terminology will have the confidence that terminology subsets and intentional constraints, CTDs and LDCs address the needs of clinical users, are clinically correct and clinically safe.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021588

## **021582 Core competencies required for the development of value domains**

Those responsible for the development of value domains and terminology binding **shall** demonstrate the following core competencies:

- An understanding of the different types of medical nomenclatures, their structures and purpose;
- Ability to describe or explain:
  - the business case for and impact of use of terminology,
  - terminology components and structure principles,
  - terminology reference sets, custom subsets, CTDs and LDCs,
  - the development considerations and processes for the creation and maintenance of value domains (including CTDs and LTDs if applicable);
- Clinical knowledge in the relevant area of development;
- Ability to identify and explain the impact of decisions around the development of value domains on clinical decision-making, clinical decision support, clinical information recording, reuse and sharing of data to support care;
- An understanding of relevant areas of the information model and the use of the healthcare software system; and
- An understanding of and ability to identify implementation issues relevant to the creation and maintenance of the value domains.

**Priority**            Mandatory

**Applicable to**    UC.005

### **Additional Notes**

The development of value domains that are correct, complete, unambiguous and relevant is not a simple task. This requirement therefore ensures that personnel demonstrate core competencies.

In most cases, no single person will have the complete set of core competencies, as outlined in this requirement, to fulfil the role in developing value domains and terminology binding for safe application.

It is therefore expected that a number of professionals will be involved in the development process. For example, the decision of whether a terminology concept should be included or excluded in a custom subset may not always be obvious and frequently requires a sound professional judgement. If the intent of a custom subset or an intentional constraint is to record procedures in a gastroenterology unit, a gastroenterologist is to be consulted in developing the custom subset or intentional constraint.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 3.5 User documentation

### 021575 User documentation

If the organisation releases terminology as part of the healthcare software system, it **shall**, as a minimum, provide the following information to the user of the healthcare software system:

- The terminology (AMT and/or SNOMED CT-AU) and other coding systems implemented in the healthcare software system;
- The overall purpose and scope of terminology in the healthcare software system;
- Complete record of all terminology bindings;
- The built-in or default intentional constraints imposed on each terminology-enabled data field by software designers and developers, and how such constraints may be overridden, turned off, or changed by the user;
- Guidelines and instructions on configuration or optimisation of search algorithms (e.g. indexing of terminology concept descriptions or defining word equivalents);
- Instructions on how to identify the terminology release version in the healthcare software system;
- Existence of CTDs and LDCs for each terminology-enabled data field, including the traceability to corresponding terminology concepts; and
- Instructions on the use of alternative approaches to recording, storing and exchange of clinical information.

**Priority** Conditional

**Applicable to** UC.005, UC.006, UC.007

#### Additional Notes

The user documentation needs to contain the above information as a minimum in order to help the user benefit from using terminology for capturing and presenting clinical information.

**021576      User documentation**

If a user has the ability to integrate terminology releases in the healthcare software system, the organisation developing the healthcare software system **shall** provide the following information to those using the healthcare software system:

- The overall purpose and intended scope of the healthcare software system;
- The purpose and scope of each terminology-enabled data field;
- The types of clinical information or value domains supported or intended for use;
- The built-in or default intentional constraints imposed on each terminology-enabled data field by software designers and developers, and how such constraints may be overridden, turned off, or changed by the user;
- How to transform the terminology release files into the correct format supported by the healthcare software system for integration;
- Guidelines and instructions on how to integrate a new terminology release into the healthcare software system;
- Guidelines and instructions on how to adequately maintain terminology within the healthcare software system;
- Guidelines and instructions on configuration or optimising of search algorithms, if applicable (e.g. indexing of terminology concept descriptions or defining word equivalents); and
- The recommendation to obtain advice and support from NCTIS (help@nehta.gov.au) in relation to terminology, if required.

**Priority**            Conditional

**Applicable to**    UC.006, UC.007

**Additional Notes**

The user documentation needs to contain the above information as a minimum in order to help the user benefit from using terminology effectively and appropriately.

## 4 Requirements for the mapping process

The requirements in this section apply to those organisations developing terminology maps or developing healthcare software systems supporting terminology maps. The requirements focus on the strategies, plans, business activities, tools, and documentation that constitutes a suitable process for terminology maps development.

If the organisation does not release terminology map data with its software, the organisation should raise awareness of these requirements among their users.

Requirements apply to an organisation, within the context of relevant use cases. Requirements listed as mandatory must be met by the organisation. Conditional requirements are treated as mandatory, provided the condition stated in the requirement is satisfied. Recommended requirements are optional, but strongly encouraged.

### 4.1 Purpose of the mapping

#### **021596** Purpose of mapping

The purpose of mapping **shall** be clearly defined and documented.

**Priority** Mandatory

**Applicable to** UC.001

#### **Additional Notes**

Each map must have a defined purpose. A map is built for a particular purpose, and may share the same purposes as other maps. The purpose of a map influences decisions made about how to map those concepts that do not have exact comparisons between the local or proprietary code system and terminology.

Additional information is provided in section 3.5 of the AMT mapping guidelines [NEHTA2012b] and section 3.3 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021597      Relevance of the purpose of mapping**

The purpose of mapping **should** be consistent with the intent of the terminology.

**Priority**            Recommended

**Applicable to**    UC.001

**Additional Notes**

Additional information is provided in section 3.5 of the AMT mapping guidelines [NEHTA2012b] and section 3.3 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021598      Scenarios of intended use of the maps**

Specific scenarios describing the intended use of the maps **shall** be clearly defined and documented.

**Priority**            Mandatory

**Applicable to**    UC.001

**Additional Notes**

Additional information is provided in section 3.5 of the AMT mapping guidelines [NEHTA2012b] and section 3.3 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021599      Relevance of the scenarios**

A quality check **shall** be in place to ensure the scenarios of intended use of the maps are consistent with the defined purpose of mapping.

**Priority**            Mandatory

**Applicable to**    UC.001

**Additional Notes**

Additional information is provided in section 3.5 of the AMT mapping guidelines [NEHTA2012b] and section 3.3 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021600 Intended users of the maps**

Intended users of the maps **shall** be clearly identified based on the scenarios of intended use of the maps.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

Additional information is provided in section 3.5 of the AMT mapping guidelines [NEHTA2012b] and section 3.3 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021601 terminology concept hierarchies/levels**

The terminology concept hierarchies or level(s) chosen to be mapped **shall** provide the precision and the granularity required for the scenarios of intended use of the maps.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

To ensure precision and granularity, the appropriate hierarchy should be selected during mapping e.g. a diagnosis of haematoma would use the Clinical Finding, not the Body Structure hierarchy concept. Also, a map for clinical use would map descriptions that have the same meaning, or if one is not available in the target system, a clinically appropriate parent concept is to be selected.

Additional information is provided in section 3.6 of the AMT mapping guidelines [NEHTA2012b] and section 3.4 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021602      Documentation on the terminology concept hierarchies or levels**

The terminology concept hierarchies or level(s) chosen to be mapped **shall** be documented with relevant justifications.

**Priority**            Mandatory

**Applicable to**    UC.001

**Additional Notes**

Additional information is provided in section 3.6 of the AMT mapping guidelines [NEHTA2012b] and section 3.4 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021603      terminology reference set(s)**

Where the scope and the context of an existing terminology reference set supports the defined purpose of mapping, that reference set **shall** be chosen as the reference set from which to select the map targets.

**Priority**            Mandatory

**Applicable to**    UC.001

**Additional Notes**

Additional information is provided in section 3.6 of the AMT mapping guidelines [NEHTA2012b] and section 3.4 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021604 Source concepts**

The decisions on which source concepts to include or exclude in mapping **shall** be based on the specific scenarios of the maps.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

Additional information is provided in section 3.6 of the AMT mapping guidelines [NEHTA2012b] and section 3.4 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021605 Documentation on the source concepts**

The decisions on which source concepts to include or exclude in mapping **shall** be documented.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

Additional information is provided in section 3.6 of the AMT mapping guidelines [NEHTA2012b] and section 3.4 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 4.2 Personnel

### 021606 Core competencies required for the development of terminology maps

Those responsible for the development of terminology maps for use in the healthcare software system **shall** demonstrate the following core competencies:

- Ability to describe or explain:
  - the business case for, as well as the impact of using maps,
  - the clinical nomenclatures used in the map including their structure, purpose and rules,
  - terminology reference sets, custom subsets, CTDs and LDCs,
  - the development considerations and processes for the creation and maintenance of a mapping;
- Clinical knowledge in the relevant area of development;
- Ability to identify and explain the impact of decisions around the development of a mapping on clinical decision-making, clinical decision support, clinical information recording, reuse and sharing of data to support care; and
- An understanding of and ability to identify implementation issues relevant to the creation and maintenance of the mapping.

**Priority** Mandatory

**Applicable to** UC.001

#### Additional Notes

Additional information is provided in section 3.6 of the AMT mapping guidelines [NEHTA2012b] and section 3.4 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

In most cases, no single person will have the complete set of core competencies, as outlined in this requirement, to fulfil the role in developing terminology maps for safe application. It is therefore expected that a number of professionals will be involved in the development process.

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021607 Mapping manager**

A mapping manager **shall** be assigned to oversee the overall mapping process.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

The mapping manager may also perform additional tasks beyond the responsibility of overseeing the mapping process.

It is expected that the mapping manager will be part of the group of skilled personnel responsible for developing the maps (refer to requirement 021606).

Additional information is provided in section 3.6 of the AMT mapping guidelines [NEHTA2012b] and section 3.4 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021608 Mapping team**

The mapping team **should** consist of the following defined roles:

- Mapping specialist;
- Clinical map adviser; and
- Technical adviser.

**Priority** Recommended

**Applicable to** UC.001

**Additional Notes**

Additional information is provided in section 3.6 of the AMT mapping guidelines [NEHTA2012b] and section 3.4 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 4.3 Software tools

### 021609 Tools used

Tools to be used in mapping **should** be evaluated to ensure they meet the needs of the mapping exercise.

**Priority** Recommended

**Applicable to** UC.001

#### Additional Notes

Mapping tools to be used should be evaluated against requirements outlined in the AMT and SNOMED CT-AU mapping guidelines. Additional information is provided in section 3.7 of the AMT mapping guidelines [NEHTA2012b] and section 3.5 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

### 021610 Use of the tools in the mapping process

An explanation of how the tools were used throughout the mapping process including pre-processing **should** be documented.

**Priority** Recommended

**Applicable to** UC.001

#### Additional Notes

Additional information is provided in section 3.7 of the AMT mapping guidelines [NEHTA2012b] and section 3.5 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 4.4 Risk management

### 021611 Risk management

Identification of risks and the required steps to mitigate the risks of incorrect maps **shall** be undertaken and documented.

**Priority** Mandatory

**Applicable to** UC.001

#### Additional Notes

To minimise patient safety risks associated with the use of terminology maps, a risk management approach or plan for patient safety risks should be clearly defined prior to commencing the mapping activity and should be followed throughout the entire mapping process through to validation, production release and ongoing maintenance. Additional information is provided in section 2.7 of the AMT mapping guidelines [NEHTA2012b] and section 3.6 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 4.5 Pre-processing the map source

### 021612 Documentation on pre-processing

If the pre-processing is undertaken on the source concepts as part of the mapping process, the following information **shall** be recorded:

- Type of change (rule-based automated changes or individual manual changes);
- Descriptions of the changes;
- Concept description (e.g. preferred term) the changes are made to; and
- Reasons for the changes made.

**Priority** Conditional

**Applicable to** UC.001

#### Additional Notes

Additional information is provided in section 3.9 of the AMT mapping guidelines [NEHTA2012b] and section 3.7 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021613 Meanings of the source concepts after pre-processing**

If the pre-processing is undertaken on the source concepts as part of the mapping process, the changes made **shall not** alter the meaning of the source concepts.

**Priority** Conditional

**Applicable to** UC.001

**Additional Notes**

Additional information is provided in section 3.9 of the AMT mapping guidelines [NEHTA2012b] and section 3.7 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 4.6 Matching the source to the target

**021614 Automated mapping**

Any matching rules or patterns used by the software tool to automatically map the source to the target **shall** be clinically appropriate for the intended use of the maps.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

This requirement requires those responsible for mapping to evaluate that the rules set up in the tool are in line with the intended use of the maps. For example, ideally the tool would allow terminology content to be filtered by hierarchy or reference set. When applying the filter, the appropriate hierarchy or reference set should be applied. In addition, when developing a map for clinical use the tool would have a rule to prevent mapping to inactive content.

Additional information is provided in section 3.10 of the AMT mapping guidelines [NEHTA2012b] and section 3.8 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021615 Mapping process**

During the development of maps, the source concept identifier and the target concept identifier **shall** be recorded as part of the map information. The terminology description identifier **shall not** be used as the primary identifier in the map.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

Additional information is provided in section 3.10 of the AMT mapping guidelines [NEHTA2012b] and section 3.8 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021616 Acceptable matches**

Only the following type of matches between the map source and the map target **shall** be released for implementation in healthcare software system:

- Lexical and semantic match (same words used and same meaning); and
- Semantic match where no lexical match is available.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

Additional information is provided in section 3.10 of the AMT mapping guidelines [NEHTA2012b] and section 3.8 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021617**      **fully specified name (FSN)**

The descriptions of the source and target concepts, that unambiguously describe the concepts, **shall** be used to verify the map or map the source concept to the target concept. Where the concept is a terminology concept, the FSN **shall** be used.

**Priority**              Mandatory

**Applicable to**      UC.001

**Additional Notes**

FSNs represent the formal, unambiguous meaning of the terminology concept. Terminology concepts have one or more 'synonyms'. Unlike formal FSNs, synonyms are common names for concepts. Synonyms are not unique i.e. two concepts may both have synonyms with the same text while still having differing description identifiers. Synonyms thereby introduce some ambiguity for the sake of usability [NEHTA2013]. For this reason, it is critical to use FSNs as the basis for verification of mapping or the development of maps in order to avoid deviating from the true meaning of a terminology concept.

Where mapping is performed, the preferred term may be used as it offers better matching potential. In such cases, the FSN must be available so that the outcome of the mapping process can be verified for correctness since terminology descriptions may not be unique.

## **4.7**      **Issues and conflicts resolution**

**021618**      **Issue resolution**

Issues encountered during the mapping process **shall** be recorded.

**Priority**              Mandatory

**Applicable to**      UC.001

**Additional Notes**

Additional information is provided in section 3.11 of the AMT mapping guidelines [NEHTA2012b] and section 3.10 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021619 Conflict resolution**

Conflict resolution process followed during the mapping process and related decisions made **shall** be recorded.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

A suitable conflict resolution strategy is required to resolve all issues identified by any part of the validation process described above. This process requires clinical input and is usually led by the mapping manager in order to ensure consistent application of mapping decisions developed during the mapping process.

Additional information is provided in section 3.11 of the AMT mapping guidelines [NEHTA2012b] and section 3.10 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 4.8 Validation of the maps

**021621 Validation**

The developed maps **shall** be validated using a documented validation process relevant to:

- The purpose of mapping; and
- Patient safety risks associated with using the developed maps.

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

Additional information is provided in sections 3.5, 3.8 and 3.12 of the AMT mapping guidelines [NEHTA2012b] and section 3.8, 3.9 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

#### **021622 Validating automatically generated maps**

If automated mapping was used to generate maps, each map in the final output **shall** be manually validated and be corrected where it was found to be incorrect.

**Priority** Conditional

**Applicable to** UC.001

##### **Additional Notes**

Additional information is provided in sections 3.5, 3.8 and 3.12 of the AMT mapping guidelines [NEHTA2012b] and section 3.8 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## **4.9 Traceability**

#### **021623 Traceability of map entries**

As a minimum, the following information **shall** be recorded and be maintained for each map:

- Who performed the map or modification of the map;
- How the map was established;
- When every change was made against which versions of the source and target code systems the map was performed.

**Priority** Mandatory

**Applicable to** UC.001

##### **Additional Notes**

Additional information is provided in sections 3 of the AMT mapping guidelines [NEHTA2012b] and section 3 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 4.10 User documentation

### 021624 Release documentation

As a minimum, documentation containing the following information **shall** be documented and provided with each release or each revision of a map set:

- The purpose of the maps (how the map should be used);
- The format of the release data (including description for each field);
- Details of any rules, algorithms or processes to be applied by the clinical systems, if such an application is required before using the maps;
- Map set version;
- Name of the source coding system;
- Coding system indicator of the source coding system;
- The release date or version of the source coding system;
- The name of the target coding system (i.e. AMT or SNOMED CT-AU);
- Coding system indicator of the target coding system; and
- The release date or version of the target coding system, if the map version is not the same as the target coding system version.

**Priority** Mandatory

**Applicable to** UC.001

#### Additional Notes

The information required by this requirement is either used by the organisation or user, and is important to assist developers and administrators in implementing, configuring and updating map data in the healthcare software system.

The version of the map set may be the same as the release version of the target coding system (i.e. AMT or SNOMED CT-AU), as this will allow an unambiguous method of determining if the map has become outdated due to a more recent terminology release published by NCTIS. Alternatively, the map version is the date the map was reviewed and updated. Regardless of the approach, the map version must convey sufficient information to ensure proper maintenance of the maps.

The coding system indicator refers to information allowing the coding system to be classified. To identify the coding system, the following options are available:

- Unique code system namespace;
- The SNOMED CT-AU and AMT version3 OID ("2.16.840.1.113883.6.96");
- The AMT version 2 OID ("1.2.36.1.2001.1004.100");
- The HL7 v2 table 396 code "SCT" for SNOMED CT-AU;
- The HL7 v2 table 396 code "AMTv2" for AMT version 2;
- The HL7 v2 table 396 code "SCT" for AMT version 3; or
- Some other appropriate method, including site-specific agreements for formats that do not include the capacity to represent the code system.

Additional information is provided in sections 3.16 of the AMT mapping guidelines [NEHTA2012b] and section 3.12 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for

**021624 Release documentation**

meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021625 Map data for release**

As a minimum, the following information **shall** be documented and be released for each map, with each release or revision of the maps:

- Unique identifier of the map;
- Map type;
- Unique identifier of the source concept;
- Source concept description;
- Source version (if appropriate)
- Target terminology concept identifier; and
- Target terminology description (i.e. preferred term).

**Priority** Mandatory

**Applicable to** UC.001

**Additional Notes**

The information required by this requirement is either used by the organisation or user, and is important to assist developers and administrators in implementing, configuring and updating map data in the healthcare software system.

Additional information is provided in sections 3.16 of the AMT mapping guidelines [NEHTA2012b] and section 3.12 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021756      User documentation**

If a user has the ability to integrate terminology maps in the healthcare software system, the organisation developing the healthcare software system **shall** provide the following information to those using the healthcare software system:

- The overall purpose and intended scope of the healthcare software system;
- The purpose and scope of each data field that support mapping;
- The types of clinical information supported or intended for use;
- The built-in or default intentional constraints imposed on each data field supporting mapping by software designers and developers, and how such constraints may be overridden, turned off, or changed by the user;
- How to transform terminology maps into the correct format supported by the healthcare software system for integration;
- Guidelines and instructions on how to integrate terminology maps into the healthcare software system;
- Guidelines and instructions on how to adequately maintain terminology maps within the healthcare software system; and
- The recommendation to obtain advice and support from NCTIS ([help@nehta.gov.au](mailto:help@nehta.gov.au)) in relation to terminology, if required.

**Priority**              Conditional

**Applicable to**    UC.002, UC.003

**Additional Notes**

The user documentation needs to contain the above information as a minimum in order to help the user benefit from using terminology effectively and appropriately.

## **5 Requirements for terminology data integration and maintenance**

The requirements in this section apply to those organisations developing healthcare software systems or integrating (i.e. implementing, importing or updating) terminology into healthcare software systems. These requirements are relevant for integration of terminology maps or value domains into healthcare software systems.

If the organisation does not release terminology with its software, the organisation should raise awareness of these requirements among their users.

Meeting the requirements in this section allows organisations to be certain that terminology contents are accurately implemented and safe to use in healthcare software systems.

Requirements apply to an organisation, within the context of relevant use cases. Requirements listed as mandatory must be met by the organisation. Conditional requirements are treated as mandatory provided the condition stated in the requirement is satisfied. Recommended requirements are optional, but strongly encouraged.

## 5.1 Quality assurance during integration and maintenance

### **021628 Ensuring terminology content integration meets acceptable quality standards**

The process of implementing, integrating and maintaining terminology value domains, including CTDs and LDCs and terminology maps in the healthcare software system **shall** incorporate quality controls and **shall** be supported by local policies and management procedures.

**Priority** Mandatory

**Applicable to** UC.004, UC.008

#### **Additional Notes**

The intent of this requirement is to ensure that terminology content integration or implementation exercises are performed correctly without the introduction of errors that could compromise the integrity of the terminology or result in misinterpretation or loss of clinical information.

The integration process with no quality, risk or governance controls will produce an output that will likely be clinically unsafe and not fit for use. It is therefore important that the organisation undertaking the integration process ensures that healthcare software system assesses, records, stores, displays and exchanges clinical information safely and correctly.

Where the organisation has allowed the capability for the user to develop, import or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where terminology release files, including reference sets and custom subsets, are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021744

## **021744      Quality controls for terminology integration**

The process of integrating and maintaining terminology value domains (including CTDs and LDCs) and terminology maps **should** incorporate at least the following quality controls:

- Ensure an integration process was followed and the updated value domains or terminology maps align with the broader scope and purpose of terminology adoption;
- Ensure each terminology binding is consistent with the defined scope and purpose of the value domain and associated information model elements;
- Ensure integrated value domains allow clinical users to easily find the most relevant or appropriate terminology concepts to express what was originally intended;
- Ensure correct functioning of the healthcare software system in preventing the display of synonymous concepts;
- Ensure terminology maps are correct in the healthcare software system and in messaging for information exchange;
- Ensure integrated value domains are complete and include all mandatory components;
- Ensure all terminology data stores (e.g. database tables) in the healthcare software system were updated in accordance with the scope of the integration exercise;
- Ensure the completion of a review of historical records to ensure the integration exercise has not compromised data integrity;
- Ensure the completion of a review of the entire data continuum and across all workflows in the healthcare software system after the integration exercise; and
- Ensure the latest terminology release data has been used.

**Priority**                      Recommended

**Applicable to**      UC.004, UC.008

### **Additional Notes**

The integration of terminology into the healthcare software system requires adequate quality controls to ensure clinical safety risk are not introduced during the process, and to ensure the healthcare software system is functioning correctly and supports the needs of clinical users.

Those responsible for overseeing the integration process need to understand this requirement only identifies a limited set of recommended quality controls, and that additional quality controls are needed that best align with organisational policies, standards and procedures.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021628

## 5.2 Review and validation

### 021745 Periodic reviews of terminology in the healthcare software system

Upon completion of integrating value domains or terminology maps into the healthcare software system, the healthcare software system **shall** be reviewed for relevance, completeness and clinical correctness through the entire data continuum and across all workflows.

**Priority** Mandatory

**Applicable to** UC.004, UC.008

#### Additional Notes

This requirement reduces the risk of using terminology in the healthcare software system that is no longer relevant or no longer available for a particular terminology-enabled data field.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021754

### 021629 Release version

The review process **shall** require a check that the terminology value domains or maps for integration into the healthcare software system do not contain terminology release content older than 180 days. Terminology data for integration **shall** come from the most recent NCTIS release if there has been no release in the past 180 days.

**Priority** Mandatory

**Applicable to** UC.004, UC.008

#### Additional Notes

This is a licensee obligation [IHTSDO2009], [NEHTA2009]. NEHTA reserves the right to vary the terms of this agreement of 180 days release cycles.

Where the organisation has allowed the capability for the user to develop, import or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where terminology release files, including reference sets and custom subsets are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 5.3 Maintenance practices

### 021747 Maintenance of terminology data in the healthcare software system

If current value domains in the healthcare software system are redundant, out of date, irrelevant, incorrect or ambiguous, the following actions **shall** be taken where required:

- Where terminology concepts were made inactive in the terminology release, ensure those terminology concepts are made inactive in the healthcare software system;
- The terminology descriptions of inactive concepts, regardless of state (inactive/active), are not to be displayed in the GUI for recording and storing of clinical statements;
- Where terminology descriptions were made inactive in the terminology release, ensure those terminology descriptions are made inactive in the healthcare software system;
- Maintain inactive terminology concepts, description and other supporting relationships and other components (e.g. description IDs) in the healthcare software system to support the display and exchange historical clinical information;
- Maintain documentation in accordance with changes made to the value domains, information model and the healthcare software system; and
- Review and update value domains impacted by change.

**Priority**                      Mandatory

**Applicable to**          UC.008

#### Additional Notes

The intent of this requirement is to ensure integrity of terminology in the healthcare software system and to ensure that the terminology data reflects that of the terminology release made available by the NCTIS.

The design of the healthcare software system, in relation to the storage and exchange of clinical information, including decision support protocols, might require inactive terminology concepts to be kept in the healthcare software system so that historical clinical information is still available and processable.

Where the organisation has allowed the capability for the user to develop, import or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where terminology release files, including reference sets and custom subsets are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021630 Maintenance of CTDs**

If CTDs are in use, they **shall** be reviewed for relevance and clinical correctness. If CTDs are redundant, out of date, irrelevant, incorrect or ambiguous, the following actions **shall** be taken where appropriate:

- Update CTDs in the healthcare software system if only *minor changes* are required.
- Inactivate CTDs in the healthcare software system if *major changes* are required:
  - Either develop new CTDs or use the terminology concept's description (i.e. preferred term), or
  - Update impacted value domains accordingly.
- Inactivate CTDs in the healthcare software system if associated terminology concepts in the terminology release were made inactive:
  - Where the CTDs belong to value domains in use for the purpose of recording and storing clinical statements, ensure those CTDs are no longer available in the GUI;
  - If relevant, develop new CTDs for those selected terminology concepts;
  - Update impacted value domains accordingly;
  - Maintain inactive terminology concepts and CTDs in the healthcare software system to support the display and exchange historical clinical information.
- Review and update the scope of relevant terminology-enabled data fields for recording and storing clinical statements and refine the selection of reference sets, or development of custom subsets and intentional constraints.
- Maintain documentation in accordance with changes made to the CTDs, value domains and/or terminology-enabled data fields in the healthcare software system.

**Priority** Conditional

**Applicable to** UC.008

**Additional Notes**

The intent of this requirement is to address situations where terminology in conjunction with CTDs is used in the healthcare software system and is incoherent, out of date or causes confusion, resulting in the risk of recording incorrect clinical statements that may be used in making clinical decisions regarding a person's healthcare. Changes to terminology through new releases may cause issues with existing CTDs in use.

'Minor changes' to the CTDs are those changes that do not alter the meaning of the CTD. Minor changes are considered changes in capitalisation, punctuation, spelling, acronym expansion or word order revision. Such changes are sometimes necessary in order to achieve a consistent and predictable presentation style, but are allowed only if they do not change the concept's meaning [IHTSDO2014b]. Any other changes are considered major, and require CTDs to be made inactive as retired, duplicate, outdated, ambiguous, erroneous, moved-elsewhere or limited [IHTSDO2014a].

The design of the healthcare software system, in relation to the storage and exchange of clinical information, including decision support protocols might require inactive CTDs to be kept in the healthcare software system so that historical clinical information is still available and processable.

Where terminology mapping is used in the healthcare software system, CTDs may not be relevant.

Where the organisation has allowed the capability for the user to develop, import or customise maps in the healthcare software system it releases, the user is responsible for

**021630      Maintenance of CTDs**

meeting this requirement. Where terminology release files, including reference sets and custom subsets are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021748 Maintenance of LDCs.**

If LDCs are in use, they **shall** be reviewed for relevance and clinical correctness. If LDCs are redundant, out of date, irrelevant, incorrect or ambiguous, the following actions **shall** be taken where appropriate:

- Update LDCs in the healthcare software system if only *minor changes* are required.
- Inactivate LDCs in the healthcare software system if *major changes* are required:
  - Develop new LDCs;
  - Update impacted value domains accordingly;
  - Maintain the retired LDCs in the healthcare software system to support the display and exchange historical clinical information.
- Inactivate LDCs in the healthcare software system if the current terminology release contains semantically equivalent active terminology concepts:
  - Where the LDCs, belonging to value domains are in use for the purpose of recording and storing clinical statements, ensure those LDCs are no longer available in the GUI;
  - Update impacted value domains accordingly, to enable the use of the newly identified terminology concepts;
    - Maintain an association between the inactive LDCs and the new terminology concepts;
  - Maintain inactive LDCs in the healthcare software system to support the display and exchange historical clinical information.
- Review and update the scope of relevant terminology-enabled data fields for recording and storing clinical statements and refine the selection of reference sets, or development of custom subsets and intentional constraints.
- Maintain documentation in accordance with changes made to the LDCs, value domains and/or terminology-enabled data fields in the healthcare software system.

**Priority** Conditional

**Applicable to** UC.008

**Additional Notes**

The intent of this requirement is to address situations where terminology in conjunction with LDCs is used in the healthcare software system and is incoherent, out of date or causes confusion, resulting in the risk of recording incorrect clinical statements that may be used in making clinical decisions regarding a person's healthcare. Changes to terminology through new releases may cause issues with existing LDCs in use.

If it is found that previous versions of terminology releases do not fulfil the needs of users, LDCs may be used instead. If the NCTIS is alerted to such cases by the users and can address the gaps with an update to the terminology, the review process mandated in this requirement will allow organisations and users to ensure terminology in the healthcare software system is fit for use.

'Minor changes' to the LDCs are those changes that do not alter the meaning of the LDC. Minor changes are considered changes in capitalisation, punctuation, spelling, acronym expansion or word order revision. Such changes are sometimes necessary in order to achieve a consistent and predictable presentation style, but are allowed only if they do not change the concept's meaning [IHTSDO2014b]. Any other changes are considered major, and require the LDC to be made inactive as retired, duplicate, outdated, ambiguous, erroneous, moved-elsewhere or limited [IHTSDO2014a].

**021748 Maintenance of LDCs.**

The design of the healthcare software system in relation to the storage and exchange of clinical information, including decision support protocols, might require inactive LDCs to be kept in the healthcare software system so that historical clinical information is still available and processable.

Where the organisation has allowed the capability for the user to develop, import or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where terminology release files, including reference sets and custom subsets are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021631 Maintenance of maps**

If the healthcare software system uses terminology maps, and a new version of the maps get updated in the healthcare software system as a result of an update to either the source or the target coding system, a review of the healthcare software system **shall** ensure all storage locations (e.g. database tables) of the source, target and map data are reviewed and updated in accordance with the new version of the maps.

**Priority** Conditional

**Applicable to** UC.004

**Additional Notes**

The intent of this requirement is to ensure that all storage locations are updated in the healthcare software system so that the integrity of the entire map set is maintained from its development through to integration and use. This requirement applies where the healthcare software system stores and access maps through a dispersed approach (e.g. in databases containing map data in second or third normal forms).

Where the organisation has allowed the capability for the user to develop, import or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021749 Notification of change to clinical users**

An impact analysis **shall** be undertaken to determine the effect that changes to value domains will have on clinical users. Where there will be an impact on clinical users of the healthcare software system, such changes **shall** be communicated across the entire community of clinical users and alternative approaches to the use of the healthcare software system **shall** be explained, where required.

**Priority** Conditional

**Applicable to** UC.008

**Additional Notes**

The changes to terminology content in the healthcare software system may impact clinical users. For example, a commonly used terminology concept was retired, and therefore is no longer available in the GUI for recording and storing of clinical statements. If clinical users are not made aware of such changes and are not offered alternative options, they may not be able to use the healthcare software system to support the delivery of safe healthcare.

Where the organisation has allowed the capability for the user to develop, import or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 6 Requirements for ongoing management of terminology in use

The requirements in this section apply to those responsible for supporting clinical users in using terminology in the healthcare software system.

If the organisation developing the healthcare software system does not release terminology with its software and is not responsible for supporting ongoing operations in relation to the use of terminology, the organisation should raise awareness of these requirements among their users.

Requirements apply to an organisation within the context of relevant use cases. Requirements listed as mandatory must be met by the organisation. Conditional requirements are treated as mandatory provided the condition stated in the requirement is satisfied. Recommended requirements are optional, but strongly encouraged.

### 6.1 Issue resolution and response process

#### **021738 Issue resolution and response process**

An issue resolution and response process **shall** be in place to address any issues users may encounter integrating, updating or using terminology in the healthcare software system.

**Priority** Mandatory

**Applicable to** UC.009

#### **Additional Notes**

The intent of this requirement is to allow those using terminology to be in the position to raise issues and for the user or organisation to have an appropriate response and resolution process in place.

Issues may be encountered after the deployment of the healthcare software system supporting terminology, or after the integration of new terminology release data into the healthcare software system. Although it is required to test the healthcare software system in relation to terminology for clinical correctness, clinical safety and quality, end to end across all workflows after development and integration of new terminology release data, it is possible that some issues may have been missed.

Examples of issues that may be encountered by those using terminology, are:

- Unable to find the relevant terminology concepts to accurately and concisely record clinical statements as originally intended;
- Confusion caused due to ambiguous, erroneous or synonymous concepts displayed in terminology-enabled data fields;
- Unable to use terminology in the healthcare software system due to a lack of training or understanding of terminology or the healthcare software system.

**Related Requirements** 021739

**021739 Resolving terminology usability issues in the healthcare software system**

As part of an issue resolution and response process, the following actions **should** be considered (where applicable) if it is found that terminology concepts, CTDs and LDCs displayed in the GUI limit the ability to record clinical statements as intended:

- Update or improve the healthcare software system;
- Migrate to the most recent terminology release;
- Revise existing constraints imposed on the relevant terminology-enabled data fields; i.e. redefine or refine the scope of terminology reference sets, custom subsets, intentional constraints;
- Record user-entered free text (original text) instead of recording the terminology concept; and/or
- Create and use LDCs as an interim strategy to address the gap in the terminology release data until the NCTIS issues an update.

**Priority** Recommended

**Applicable to** UC.009

**Additional Notes**

The intent of this requirement is promote a process that consists of a number of resolution activities that those responsible for managing terminology in production can employ to support clinical users on a day-to-day basis. An appropriate response process in place promotes the use of terminology and limits usability and clinical safety risk. For example, without a resolution process, clinical users may be forced to use terminology, CTD and LDCs that are irrelevant, out of date, incorrect or ambiguous, resulting in ambiguous or erroneous clinical statements being recorded, which in turn are used to inform healthcare delivery for the patient.

Users or organisations responsible for the maintenance of terminology in the healthcare software system are encouraged to contact the NCTIS to obtain advice and guidance where needed. Requests can be sent to [help@nehta.gov.au](mailto:help@nehta.gov.au).

**Related Requirements** 021738

## 6.2 Continuous improvement

### 021740 Continuous refinement and improvement of terminology in the healthcare software system

An improvement process **should** be in place to continuously improve the availability and relevance of terminology in the healthcare software system. The objective of the process **should** be to review user-entered free text previously recorded and stored in the healthcare software system to determine the following:

- Search and find the appropriate terminology concepts currently available in the relevant terminology-enabled data fields that could have been selected instead of entering user-entered free text. This information should direct training and education materials for clinical users.
- Search and find the appropriate terminology concepts that were not available for recording and storing in the particular terminology-enabled data field, and update the selection of reference sets or redefine custom subsets and intentional constraints accordingly.
- Request an update to the terminology release data to address the need.
- Integrate the new terminology release, containing the new terminology concepts, into the healthcare software system, while ensuring the update addresses the need originally identified.

**Priority** Recommended

**Applicable to** UC.009

#### Additional Notes

The success of this process relies on trained personnel who are available to do the review on a timely schedule, and the willingness and education of clinical users to use terminology instead of recording user-entered free text where appropriate. Choosing the appropriate terminology concepts rather than user-entered free text [IHTSDO2014a] is much preferred, since it promotes the realisation of the benefits offered by terminology.

**021743 Request of new terminology concepts from NCTIS**

Where users find that the latest terminology release data does not support the ability to author appropriate clinical statements, the NCTIS **should** be contacted to request for an update to the terminology release data.

**Priority** Recommended

**Applicable to** UC.009

**Additional Notes**

The intent of this requirement is to promote the adoption of terminology and to ensure that expected benefits from terminology adoption may be realised.

In most cases, terminology concepts have already been developed to address the need of users. It is therefore important to first determine if:

- the healthcare software system needs to be updated with the most recent terminology release;
- the developed value domains and data bindings are adequate.

If it is determined that none of the above steps would address the issue, contact the NCTIS. Requests can be sent to [help@nehta.gov.au](mailto:help@nehta.gov.au).

As an interim solution, the use of LDCs or the ability to record user-entered free text, instead of record terminology concepts may be put in place until an update to the terminology content is provided by the NCTIS.

**Related Requirements** 021738

## 6.3 Required policies on terminology in use

**021750 Periodic review of value domains in the healthcare software system**

Value domains in the healthcare software system **shall** be reviewed for relevance, completeness and clinical correctness on a periodic basis, as required by local policy.

**Priority** Mandatory

**Applicable to** UC.009

**Additional Notes**

The intent of this requirement is to ensure that local policies exist to require review of terminology in use to ensure it is clinically safe and fit for use.

The review may coincide with the process of integrating new NCTIS terminology release content into the healthcare software system.

**021751      Periodic review of terminology maps in the healthcare software system**

Terminology maps in use in the healthcare software system **shall** be reviewed for relevance, completeness and clinical correctness on a periodic basis, as required by local policy.

**Priority**            Mandatory

**Applicable to**    UC.009

**Additional Notes**

The intent of this requirement is to ensure that local policies exist to require review of terminology maps in use to ensure they are clinically safe and fit for use.

The review may coincide with the process of integrating updated terminology maps with new NCTIS terminology release content into the healthcare software system.

**021626      Regular update of terminology maps in the healthcare software system**

Terminology maps in use **shall** be updated with each new NCTIS terminology release or change to the map source or the map target.

**Priority**            Mandatory

**Applicable to**    UC.009

**Additional Notes**

Additional information is provided in sections 3.17 of the AMT mapping guidelines [NEHTA2012b] and section 3.13 of the SNOMED CT-AU mapping guidelines [NEHTA2014j].

Where the organisation has allowed the capability for the user to develop, integrate or customise maps in the healthcare software system it releases, the user is responsible for meeting this requirement. Where maps are part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

## 6.4 Required policies on localised content in use

### 021577 Policies on using user-entered free text instead of using terminology

Where the healthcare software system supports the ability to record and store user-entered free text instead of using terminology, policies **shall** be in place to guide clinical users in using such functionality in an appropriate manner. The policies **shall** be clearly documented and **shall** address the context under which such system usage is deemed appropriate and permitted.

**Priority** Mandatory

**Applicable to** UC.009

#### Additional Notes

The option to record user-entered free text instead of using terminology in expressing clinical statements should not be considered the norm, as such a culture of system usage will undermine the objective of receiving the benefits of using terminology. It is important for healthcare providers to appreciate this as a significant issue and to identify under which circumstances it is deemed necessary to record and store user-entered free text instead of using terminology.

The ability to use terminology to express clinical statements instead of recording user-entered free text is heavily dependent on the design of the software system and how terminology is constrained for each terminology-enabled data field. The level of training users have in terms of using the healthcare software system may also impact on the approach taken in recording clinical statements.

**Related Requirements** 021572, 021573, 021752

### 021752 Education on the use of user-entered free text instead of using terminology

Where the healthcare software system supports the ability to record and store user-entered free text instead of utilising terminology, clinical users **shall** be educated on local policies around the use of such functionality.

**Priority** Mandatory

**Applicable to** UC.009

#### Additional Notes

The option to record user-entered free text instead of using terminology in expressing clinical statements should not be considered the norm, as such a culture of system usage will undermine the objective of receiving the benefits of using terminology. It is important for healthcare providers to appreciate this as a significant issue and to identify under which circumstances it is deemed necessary to record and store user-entered free text instead of utilising terminology.

The ability to use terminology to express clinical statements instead of recording user-entered free text is heavily depended on the design of the software system and how terminology is constrained for each terminology-enabled data field. The level of training users have in terms of using the healthcare software system may also impact on the approach taken in recording clinical statements.

**Related Requirements** 021572, 021573

### **021753 Policies on creating and using CTDs**

If CTDs are to be created for use in the healthcare software system by clinical users, policies and procedures **shall** be in place, and **shall** as a minimum detail the following:

- Those authorised and responsible for maintenance (i.e. creation, retirement and review) of CTDs;
- The preconditions for fulfilment before it is deemed necessary to create or retire CTDs; and
- The context under which CTDs are deemed appropriate for use;
- Schedule for periodic reviews of CTDs in use.

The policies and procedures **shall** be clearly documented and clinical users of the healthcare software system **shall** be educated in this regard.

**Priority** Conditional

**Applicable to** UC.009

#### **Additional Notes**

The intent of this requirement is to promote a standard and well defined approach in the creation and use of CTDs. Policies should only allow a certain group of people to introduce CTDs in the workplace. Circumstances under which it is allowed to create or retire CTDs need to be defined.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021591 Policies on creating and using LDCs**

If LDCs are to be created for use in the healthcare software system by clinical users, policies and procedures **shall** be in place, and **shall** as a minimum detail the following:

- Those authorised and responsible for maintenance (i.e. creation, retirement and review) of LDCs;
- The preconditions for fulfilment before it is deemed necessary to create or retire LDCs;
- The context under which LDCs are deemed appropriate for use;
- Schedule for periodic reviews of LDCs in use.

The policies and procedures **shall** be clearly documented and clinical users of the healthcare software system **shall** be educated in this regard.

**Priority** Conditional

**Applicable to** UC.009

**Additional Notes**

The creation of LDCs should be limited to special use cases and should not be considered the norm. Allowing clinical users to freely create local concepts without introducing rigid rules and conditions will undermine the objective of receiving the benefits adopting terminology. Contacting the NCTIS regarding LDCs is strongly suggested.

If the creation of LDCs is allowed, then there are certain requirements that apply. For more information, please refer to *Clinical Terminology – Guidance for Use in Healthcare Software* [NEHTA2014h].

LDCs are different from CTDs.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**021754      Periodic review of CTDs and LDCs in the healthcare software system**

The periodic review of CTDs and LDCs in the healthcare software **should** be undertaken after each new integration process and **should** coincide with the terminology release cycles by the NCTIS.

**Priority**            Recommended

**Applicable to**    UC.009

**Additional Notes**

The intent of this requirement is to limit the risk of using CTDs and LDCs that are erroneous, outdated and incorrect or lead to confusion.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

**Related Requirements** 021745

## 6.5      **Management of localised content**

**021594      The use of LDCs with terminology as an interim strategy**

The use of LDCs **should** be an interim strategy, only employed until the current terminology content can be updated by the NCTIS where the NCTIS found a need to introduce additional terminology concepts not previously available in the terminology releases.

**Priority**            Recommended

**Applicable to**    UC.009

**Additional Notes**

The intent of this requirement is to promote a controlled approach to the creation and use of LDCs. Users need to be aware that terminology should be used where possible, and if in scope within the context of use. Because LDCs could introduce clinical safety and business risks around how clinical statements are recorded, interpreted and processed, the introduction and use of LDCs should be managed appropriately.

LDCs may not necessarily always be suitable for adoption by NCTIS, and therefore would not become part of the national terminology release. However, alternative terminology concepts may be developed to deal with gaps the LDCs were meant to address.

Users need to be aware of the intended purpose and scope of terminology and if it might be appropriate to use alternative coding systems as opposed to creating LDCs, where it is found that terminology does not address needs adequately.

**021592 Allowing the creation of LDC not found in terminology releases**

If LDCs are to be created and used in the healthcare software system for recording, storing and displaying clinical statements, it **shall** only be allowed where:

- It is clear that a semantically equivalent terminology concept in the latest terminology release is not available to express the intended meaning of the author;
- A conformant post-coordinated expression [NEHTA2014h] using terminology cannot be created to express the intended meaning of the author;
- It has been agreed across the domain (area of focus or relevance) that the LDC will represent a term or clinical expression that is commonly recorded by clinical users as free text;
- It introduces consistency and limits erroneous data entry by clinical users;
- It is not needed to exchange clinical information across organisational boundaries where LDCs are not understood or recognised; and
- A strategy exists to transition from using LDCs to terminology concepts when made available by the NCTIS.

**Priority** Conditional

**Applicable to** UC.009

**Additional Notes**

The creation of LDCs should be limited to special use cases and should not be considered the norm. Allowing clinical users to freely create LDCs without introducing rigid rules, conditions and procedures as governance, will undermine the potential benefits of adopting terminology. The NCTIS should be contacted if there is a need to create LDCs.

There are requirements that apply if the creation of LDCs is allowed. For more information, please refer to *Clinical Terminology – Guidance for Use in Healthcare Software* [NEHTA2014h].

LDCs are different from CTDs.

Where the organisation allows the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

#### **021742 Managing LDCs in use**

If LDCs are in use in the healthcare software system, a process **shall** be in place to allow periodic reviews of such concepts. The review **shall** aim to determine that each LDC is:

- still relevant and current; and
- used in a manner consistent with the intended purpose and scope.

Where LDCs are found to be inadequate, or out of date, the LDCs **shall** be retired and alternatives **shall** be put in place.

**Priority** Conditional

**Applicable to** UC.009

#### **Additional Notes**

The intent of this requirement is to mitigate the risk of users recording clinical statements that are incorrect.

When an LDC is to be removed, the appropriate action must be taken to ensure that clinical users can still use the healthcare software system. For example, where the LDC causes confusion among users and results in the authoring of ambiguous or erroneous clinical statements, it would be better to remove the LDC and replace it with a more appropriate terminology concept or LDC. Where both options are inappropriate, the option to allow users to record user-entered free text or use alternative coding systems may also be a viable solution. Whichever decision is made, those responsible for taking action need to consider the impact (e.g. clinical safety risks) of their choices.

#### **021578 Allowing the recording of user-entered free text instead of using terminology**

Recording and storing user-entered free text instead of terminology **shall** only be allowed where:

- It is clear that a semantic equivalent terminology concept cannot be found in the latest releases published by the NCTIS to express the intended meaning of the clinical statement; or
- A conformant post-coordinated expression [NEHTA2014h] using terminology cannot be created to express the intended meaning of the author.

**Priority** Mandatory

**Applicable to** UC.009

#### **Additional Notes**

The option of entering free text instead of using terminology in clinical statement should not be considered the norm, as such system usage will undermine the benefits of terminology. It is important for healthcare providers to educate clinical users appropriately.

**021579      Authoring clinical statements that consist of user-entered free text and terminology concepts**

The healthcare software system **should not** enable users to author clinical statements that consist of terminology concepts and user-entered free text.

**Priority**            Recommended

**Applicable to**    UC.009

**Additional Notes**

An example of this practice would be where the software allows a user to record or select a terminology concept, and also offers a text box next to the terminology concept where "additional information" can be entered. This would enable a user to record a concept for "bacterial infection" and enter the kind of bacteria as a note. In effect, this allows some informal post-coordination.

It might be a common occurrence for healthcare software systems to support users in recording terminology concepts with user-entered free text. However, this practice is strongly discouraged. The user-entered free text may refine, broaden or even contradict the meaning of the associated concept. This can lead to confusion by those interpreting such clinical statements. From a coding perspective, this type of functionality introduces obstacles to accurately represent the clinical statement as it was perceived and intended by the author. The way in which the GUI was designed and used by the user in recording a clinical statement will influence how and what information is recorded and the author's interpretation of its meaning. Clinical safety risks may arise where decision support algorithms make use of the encoded concept without the original text, or the manner in which the clinical statement is presented to users through information exchange.

With appropriately designed terminology-enabled data fields and appropriately constrained terminology data, software designers, developers and terminology data integrators can limit the risk of users recording ambiguous or erroneous clinical statements as a result of not being able to find the most appropriate terminology concepts to express the intended meaning of the clinical statement. If the user does not find the most appropriate terminology concept to express the clinical statement as intended, and the healthcare software system allows user-entered free text to be recorded as part of the terminology concept for clarification purposes, additional clinical safety risks may be introduced.

It is therefore important that those responsible for designing the software and those responsible for constraining and integrating terminology data into the healthcare software system work together closely to ensure the correct balance between logical software designs and appropriate aggregation of terminology data.

A systematic and carefully planned approach in selecting terminology references sets, and refining and developing custom subsets, intentional constraints and CTDs is therefore needed by the organisation responsible for the manipulation, refinement and integration of terminology data into the healthcare software system. The healthcare software system must be tested for clinical correctness, clinical safety and quality, end to end across all workflows, once implemented in the healthcare software system for each release or revision.

## **021755      Authorisation to create CTDs and LDCs**

Personnel with the following competencies **shall** be given the authority to endorse the creation and use of CTDs and LDCs:

- An understanding of the different types of medical nomenclatures, their structures and purpose;
- Ability to describe or explain:
  - the business case for and impact of use of terminology;
  - terminology components and structure principles;
  - terminology reference sets, custom subsets, CTDs and LDCs;
  - the development considerations and processes for the creation and maintenance of value domains (including CTDs and LTDs if applicable);
- Clinical knowledge in the relevant area of development;
- Ability to identify and explain the impact of decisions around the development of value domains on clinical decision-making, clinical decision support, clinical information recording, reuse and sharing of data to support care; and
- An understanding of and ability to identify implementation issues relevant to the creation and maintenance of the value domains.

**Priority**                      Mandatory

**Applicable to**          UC.009

### **Additional Notes**

The intent of this requirement is to avoid cases where any clinical user has been given the ability to create CTDs or LDCs with little or no governance in place.

Considerable knowledge and skills are needed by a combination of professionals, working together to develop CTDs or LDCs (or both), as there are numerous factors that need to be considered before CTDs or LDCs are safely introduced into production environments. The introduction of CTDs or LDCs may introduce significant clinical safety and business risks if not done appropriately.

Where the organisation has allowed the capability for the user to integrate or customise terminology releases in the healthcare software system it releases, the organisation is responsible for informing the user of their responsibility in meeting this requirement. Where terminology is part of the healthcare software system release to users, the organisation is responsible for meeting this requirement.

# Acronyms

<b>Acronym</b>	<b>Description</b>
ACHI	Australian Classification of Health Interventions
AMT	Australian Medicines Terminology
CDA	Clinical Document Architecture: an XML-based mark-up standard intended to specify the encoding, structure and semantics of clinical documents exchanged between healthcare software systems.
CTD	customised terminology description
FSN	fully specified name
GUI	graphical user interface
HL7	Health Level Seven
ICD	International Statistical Classification of Diseases and Related Health Problems
IHTSDO	International Health Terminology Standards Development Organisation
LDC	locally defined concept
LOINC	Logical Observation Identifiers Names and Codes
NCTIS	National Clinical Terminology and Information Service (within NEHTA)
OID	object identifier
PBS	Pharmaceutical Benefits Scheme
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SNOMED CT-AU	Australian extension of SNOMED CT

# Glossary

Term	Meaning
clinical information	Information about a subject of care, relevant to the health or direct treatment of that subject of care that is recorded by or on behalf of a healthcare provider [AS5021].
clinical statement	A discrete clinical record entry.
clinical user	Refers to an individual who is an end user of a healthcare software system.
coding system	A system of code sets, coding standards and code maintenance procedures together with their authorization and governance as a mechanism used to allocate a code to a represent a concept, i.e. the design of code in a domain [AS5021].
coding system indicator	An attribute value or property that uniquely identifies a coding system.
concept	<p>Refers to a clinical meaning or idea.</p> <p>A concept may have a unique numeric identifier (ConceptId). A concept is generally represented by a unique human-readable description (e.g. fully specified name (FSN)). The concept may also be formally defined in terms of its relationship with other concepts.</p>
concept model	A set of rules that determines the permitted sets of relationships between particular types of concept. The concept model specifies the attributes that can be applied to particular concepts and the ranges of permitted values for each of these attributes. There are also additional rules on the cardinality and grouping of particular types of relationships [IHTSDO2014].
concept identifier	Refers to a unique identifier (ConceptId) within the coding system that identifies a particular concept, and is designated as the value to use to identify concepts when communicating between systems. The registration of the OID or the underlying documentation for the coding system should be used to determine which symbols are designated for this purpose.
customised terminology description	<p>Customised terminology description is a description. It refers to an alternative synonym not found in the vocabulary of AMT or SNOMED CT-AU, but used within the GUI to meet specific usability needs within a given context of a local community of users (e.g. short names).</p> <p>The healthcare software system has the terminology implemented as a native interface terminology but does not display the terminology preferred terms in the GUI for some or all implemented terminology concepts. Instead the healthcare software system displays the customised terminology descriptions (CTDs) where required.</p> <p>When recording and storing terminology, the healthcare software system records the terminology concept identifier, terminology description, terminology version and the CTD that was displayed to the user at the time of recording the terminology concept.</p> <p>CTDs have undergone a premeditated development process for the purpose of meeting specific usages and care must be taken not to replace or modify the terminology release in any way. The outcome is that each CTD semantically matches the terminology concept's FSN in the NCTIS release, and therefore does not differ in meaning from the terminology concept it describes.</p> <p>The development of CTDs must not be based on other terminology synonyms (i.e. preferred or acceptable terms) as this may result in deviating from the true meaning of the terminology concept. Instead the terminology's FSN</p>

Term	Meaning
data field	<p>must be used in developing a new CTD for the terminology concept. The notion of CTDs does not refer to the modification of terminology descriptions or creation of LDCs at the time of recording clinical statements at runtime.</p>
description	<p>A description is a term or name assigned to a concept for the purpose of describing the concept. Multiple descriptions might be associated with a concept.</p>
expression	<p>A structured combination of one or more concept identifiers used to express an instance of a clinical idea [IHTSDO2014].</p>
fully specified name	<p>A fully specified name is a description. Each terminology concept has a fully specified name (FSN) intended to provide an unambiguous way to name the terminology concept. The purpose of the FSN is to uniquely describe the terminology concept and clarify its meaning. The FSN is not a commonly used terminology description or natural phrase, and would not be expected to appear in the human-readable representation of a clinical record.</p>
healthcare software system	<p>A system that deals with the collection, storage, retrieval, communication and use of health related data, and information and knowledge pertaining to subjects of care. The healthcare software system may be a standalone application or may be a combination of integrated systems, including terminology browsers or terminology servers. Terminology browsers allow the content and structure of terminology to be explored and reviewed, whereas terminology servers provide programmatic access to terminology data. Regardless of implementation type, the guidance in this document applies to those healthcare software systems using AMT or SNOMED CT-AU in one way or another. For more details on the implementation approaches, refer to the <i>SNOMED CT Technical Implementation Guide</i> [IHTSDO2014] and the <i>Australian Medicines Terminology v3 Model Technical Implementation Guide</i> [NEHTA2013b].</p>
information model	<p>A formal description of a domain through a graphical or lexical representation of concepts or data, specifying their properties, structures and interrelationships.</p>
intentional constraints	<p>Intentional constraints imposed on a particular data field refer to measures taken by system designers, developers or implementers in allowing only certain concepts, meeting certain criteria or falling under a particular conceptual category, to be available for recording and storing by the user. For example, if a data field captures clinical procedures, displayed to the user as a list of allowable descriptions, it would only display terminology concepts belonging to the SNOMED CT-AU <i>Procedure Foundation</i> reference set and would not display terminology concepts from the <i>Problem Diagnosis</i> reference set.</p> <p>Intentional constraints may be:</p> <ul style="list-style-type: none"> <li>• intentional constraints defined through system configuration;</li> <li>• intentional constraints defined through imbedded hard-coded system rules; or</li> </ul>

Term	Meaning
locally defined concept	<ul style="list-style-type: none"> <li>intentional constraints defined through inclusion or exclusion of terminology release content (e.g. reference sets) in the healthcare software system.</li> </ul> <p>A locally defined concept (LDC) is a concept, created for use by a local community of users within a defined knowledge domain, used to broaden the scope of coverage of terminology for use in a specific language, specialty or jurisdiction.</p> <p>LDCs are created and used as a transition strategy to move away from an ad hoc approach to recording, storing and displaying clinical information that may be ambiguous, contradictory, inconsistent, and unmanageable towards a more structured approach, where it is determined that the existing terminology releases do not adequately meet the requirements of the local community of users.</p> <p>If users find that the latest terminology release data do not support the ability to author appropriate clinical statements, they can contact the NCTIS obtain a namespace identifier and ask for an update to the terminology release data to address identified gaps.</p> <p>References to LDCs in this document refer only to those concepts that are used with terminology. LDCs are not CTDs, because there are no connections or links with any terminology concept, and they are not used as appropriate alternative synonyms to the synonyms found in the terminology releases.</p>
map (a.k.a. terminology map)	An index from one concept to another, sometimes using rules that allow translation from one representation to another indicating degree of equivalence.
map source	A terminology, coding scheme or classification used as the starting point for map production (in the context of mapping) [NEHTA2014h].
map target	A terminology, coding scheme or classification to which some or all of the concepts in another terminology, coding system or classification (the map source) are mapped [NEHTA2014h].
namespace identifier	<p>A number allocated to an institution that is permitted to maintain LDCs as extensions to the current terminology release content. The <i>Australian National Terminology licence agreement</i> [NEHTA2009] states: "The Licensee may not in respect of the National Release create any Standards-Based Extension or any Standards Based Derivative unless it has first been issued with a Namespace Identifier".</p> <p>The namespace identifier indicates the provenance of each terminology component. For example, in a concept in the AMT created by NEHTA, the namespace identifier is 1000036, as seen in the identifier: 2166401<b>1000036</b>103. For a non-AMT concept created by the Pharmaceutical Benefits Division (PBD) for an item in the Pharmaceutical Benefits Scheme (PBS) data file, the namespace identifier is 1000144, as seen in the identifier: 5729<b>1000144</b>108.</p>
native interface terminology	<p>The healthcare software system uses terminology in its native form such that users interact with the terminology concepts through the GUI and they are stored and shared throughout the system.</p> <p>For example, the healthcare software system displays AMT or SNOMED CT-AU (or both) preferred terms for selection or recording by the user.</p>
normal form	A representation of an expression in which none of the referenced concepts are fully defined and where there is no redundancy or duplication of meaning.

Term	Meaning
organisation	<p>In the context of this document, this refers to an organisation such as a vendor, healthcare provider or health jurisdiction involved in one or more of the following activities:</p> <ul style="list-style-type: none"> <li>• development of healthcare software systems;</li> <li>• development of terminology maps;</li> <li>• development of custom subsets/intentional constraints for native interface terminology; or</li> <li>• integration, implementation or update of terminology data in healthcare software systems.</li> </ul>
original text	<p>The original text is the text seen by the user at the time of recording a concept or expression (i.e. post-coordinated or free text) in a human-readable format. The original text may take on various forms, depending on the medium through which original text is presented. Regardless of medium, the original text accurately conveys the meaning of the clinical statement as originally intended by the author at the time of recording and storage.</p> <p>In most cases, the original text would be the same as the terminology description i.e. preferred term (a.k.a. the <i>displayName</i> in CDA) where the user sees and selects a terminology concept from the GUI.</p> <p>Alternatively, the original text would be same as the:</p> <ul style="list-style-type: none"> <li>• CTD text displayed and selected by the user;</li> <li>• text seen by the user typing a free-formed expression or a post-coordinated expression; or</li> <li>• a combination of a terminology description and user-entered free text.</li> </ul> <p>In this case the terminology description (display text or <i>displayName</i>) is different from the original text.</p>
post-coordinated expression	<p>Representation of a clinical meaning using a combination of two or more concept identifiers is referred to as post-coordination [IHTSDO2014].</p>
preferred term	<p>A concept description that is deemed to be the most clinically appropriate way of expressing a concept in the healthcare software system.</p> <p>SNOMED CT-AU and AMT v3 preferred terms are determined by the <i>acceptabilityId</i> value of '90000000000548007' (i.e. 'Preferred') defined in the Australian dialect reference set. AMT v2 preferred terms are determined by the <i>DescriptionType</i> value of '1' in the AMT v2 description release file.</p>
recording	<p>In the context of this document, recording refers to the action of data entry, by which a user populates a data field with data either by typing text, selecting items from a dropdown or list, importing, or copying and pasting from an alternative source, etc.</p> <p>This should not be confused with the storage of data in a healthcare software system.</p>
reference set	<p>A work consisting of a set of references to SNOMED CT or AMT components which may associate additional properties with components that are members of the set or which may indicate associations between members of the set and content of another nomenclature, classification or knowledge structure. The uses of reference sets include identification of subsets of SNOMED CT or AMT content, representation of alternative hierarchical structures and cross-maps to classifications.</p> <p>'Reference set' is used in this document to indicate an NCTIS published reference set such as <i>Problem/ Diagnosis</i> reference set, <i>Procedure Foundation</i> reference set, <i>Medicinal Product Pack</i> reference set, or <i>Trade Product Unit Of Use</i> reference set.</p>

<b>Term</b>	<b>Meaning</b>
runtime	The period during which a computer software program is executing.
sample map	A map created by an assessor from a sample source term to one or more target concepts.
sample set	A set of sample source terms.
sample source term	A map source term selected by the assessor to form part of a sample set.
store, storage or storing	This refers to non-volatile storage of data by keeping data in a location (e.g. system database) in such a manner that it can be retrieved by the healthcare software for processing at any time when required. Storing data results in the data being persisted until it gets removed.
subset	'Subset' and 'custom subset' are used in this document to indicate a custom portion of the terminology content, which is not an NCTIS published reference set, identified by the developer for a specific purpose.
synonym	A term that is an acceptable alternative to the preferred term as a way of expressing a concept. Synonyms allow representations of the various ways a concept may be described. Synonyms and preferred terms (unlike FSNs) are not necessarily unique. More than one concept might share the same preferred term or synonym [IHTSDO2014].
synonymous concepts	Refers to concept descriptions with the same text, independent of case and punctuation, or descriptions with similar meanings, look-alike or sound-alike.
terminology binding	An instance of a link between a terminology component (e.g. <i>ConceptId</i> ) and an information model element such as a data field, a class or an attribute in an electronic health record or message.
terminology concept	This refers to a clinical meaning identified by a unique numeric identifier (concept identifier) that never changes. Each terminology concept is represented by a unique human-readable fully specified name (FSN). The terminology concept is formally defined in terms of its relationship with other terminology concepts.
terminology concept identifier	Refers to a permanent unique numeric identifier that identifies a particular terminology concept.
terminology description	Refers to a term or name assigned to a SNOMED CT-AU or AMT concept. The AMT has adopted the SNOMED CT description types. 'Term' in this context means a phrase used to name a terminology concept. Multiple descriptions might be associated with a terminology concept identified by its concept identifier. SNOMED CT concept descriptions include fully specified names, preferred terms and synonyms. Preferred terms are recommended where the term will be displayed in GUIs. [NEHTA2012c].
terminology mapping	<p>The healthcare software system uses a local or proprietary coding system – other than AMT or SNOMED CT-AU – in its native form, such that users interact with the local or proprietary coding system through the GUI and are stored and shared throughout the system.</p> <p>The local or proprietary coding system has been mapped to AMT or SNOMED CT-AU ('terminology') terms for the purpose of transferring information externally in system-to-system messages or CDA documents.</p> <p>The terminology fully specified names (FSN) must be used to map the source concept to the target concept, to ensure that the true or full meaning of the terminology concept is understood and its scope is taken into account in the map.</p>

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<b>Term</b>	<b>Meaning</b>
terminology server	Software that provides access to terminology (or to other coding systems). A terminology server typically supports searches and navigation through concepts. A server may provide a user interface (e.g. a browser or set of screen controls) or may provide low-level software services to support access to terminology by other applications.
user	Refers to an institution that uses a healthcare software system capable of supporting terminology. A user has not developed the healthcare software system, but may have had some input during its development, installation or customisation process. A user may have the capability to integrate, update and maintain terminology maps or terminology release data such as reference sets in the healthcare software system in use.
value domain	<p>A value domain constrains the permissible values (i.e. terminology concepts) for a data element or data field.</p> <p>Value domains are reusable components and therefore, the same value domain can be associated with different data elements/data fields in different contexts. Value domains may be a terminology reference set, a combination of terminology reference sets, or custom subsets, including CTDs and LDCs. A value domain can also be realised through the application of intentional constraints.</p> <p>Value domains constrain, either by specifying a lower and/or upper bound on the range of permissible values or else by specifying a finite set of prescribed values. Such sets of prescribed values must be documented and be reflected in the relevant terminology-enabled data fields in the healthcare software system where they are relevant.</p>

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