

ePathology

Pathology Result Reporting V1.0 Feedback Report

Draft Package Document

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I. Introduction

This report is based on the feedback received on the draft Pathology Result Reporting Package v1.0. The draft Result Reporting package comprises a collective suite of specifications and supporting material which will be used for the electronic communication of pathology result information.

Feedback was obtained predominantly from peak industry bodies, peak standards bodies, government, software vendors as well as other interested parties. A total of 161 feedback responses were received.

There were a number of themes shared by the respondents including:

- More involved consultation with stakeholders during the specification development
- Longer timeframes within which to feedback

All feedback has been detailed in this report and all points will be taken into consideration for future versions of e-Pathology. We have found the feedback to be immensely valuable. NEHTA would like to thank all those who have contributed.

Please note the terms e-Pathology package and e-Pathology program are used interchangeably in this document.

2 Results Reporting Feedback and Responses

2.1 General Feedback

2.1.1 AHML Feedback

AHML-1 Time frame for comment was way too short

NEHTA agrees and will introduce the following review processes for future versions:

- Adopt the review process used by Standards Australia To ensure greater efficiency with the process
- Provide a longer feedback timeframe
- Conduct workshops to discuss and resolve outstanding issues that NEHTA and contributors cannot resolve within the material development period.

AHML-2 I don't believe asking for feedback/comments constitutes collaboration

NEHTA will enlist input from stakeholders during the material development phase of future versions to ensure that the proposed solution addresses industry needs.

AHML-3 Mention of this being put through the Standards process but this hasn't been put on the Standards work program for 2008-2009

NEHTA has recently joined the IT-14-6-5 Working Committee to start to investigate how this can be done. Standards Australia is currently undergoing some changes also. NEHTA and Standards Australia are presently ascertaining how we will work together in the future.

AHML-4 Conformance/Compliance/Certification are an integral part, they are mentioned as proposed work but these are things which need to be developed in parallel not as a 'tack on' to the package.

NEHTA is also currently developing a strategy and related work program for conformance, compliance and certification. We are in the process of socialising this initially with members of Stakeholder Reference Forum with a view to furthering its development.

All future e-Pathology material will incorporate elements of conformance, compliance and certification throughout the development process.

AHML-5 Have there been any thoughts about compliance between versions of the package?

Each of the e-Pathology Packages is intended to build upon the previous version (not replace). Therefore conformance / compliance will also grow between package versions.

AHML-6 Is this package a whole or nothing or can parts be implemented?

Everyone's path to an interoperable environment is different. The migration pathway may involve implementation of all or parts of the package at any given timeframe. Where able to do so (and it makes good business sense in the short term), parts of the package will be implementable.

AHML-7 Are there any tools and support to implement this?

NEHTA is investigating tools to assist with implementation.

NEHTA has implemented a Reference Platform. This platform is intended to showcase the specifications provided as part of the package in a working environment. This platform also assists as an implementation tool.

Code and, where appropriate, software forming the reference platform is available for implementers to provide a jumpstart for implementers in their adoption of web services.

Tools for implementing clinical terminology and the clinical information specifications are also being investigated.

AHML-8 When will the 'Implementation Guide' mentioned be available and how/who are these being developed? (People with Implementation experience, will there be collaboration with IHE?)

Drafts of implementation guides are being developed by staff at NEHTA in their respective areas of expertise. These guides will be tabled with the industry to determine how to develop them together moving forward.

IHE collaboration provides a useful methodology for interoperability testing and for product conformance testing. As part of our formative certification strategy, we are interested in collaboration with IHE where the IHE methodology may be applied to local profiles.

Results Reporting Feedback and Responses

AHML-9 The documentation seems to be in between focus, it's not high level but it's not detailed enough to implement

This feedback will be incorporated into the newly designed package material.

AHML-10 Needs more detail around what problems are trying to be addressed and how different parts of the package address these

To date the package material addresses the problems identified by the Pathology professional bodies. Further investigation and collaboration is required by the standards bodies, the software industry and the government, including NEHTA, to determine the full set of issues that the e-Pathology program should be addressing.

The package material will then provide detailed summaries of what the material is, how it addresses the issues and to whom the material is aimed.

2.1.2 Royal College of Pathologists Australasia (RCPA)

RCPA-1 The volume of documentation provided was very significant and this, coupled with the fact that the subject matter is quite complex for many, is likely to have impacted on the capacity of relevant committee members to provide comment.

I am therefore able to provide only limited feedback, and it is possible that this does not represent a broad view of the Fellowship.

If NEHTA requires more detail or a clearer position from the College on any particular points, I am happy to seek further advice but would need NEHTA to identify more specifically the issues to which it would like the College to respond.

A longer feedback timeframe will enable respondents to have more time to digest the information and provide feedback and raise questions. This will also allow a change in direction if needed.

RCPA 2 I am advised that the suggestion was made at the workshop that NEHTA contact the Pathology Associations Committee (PAC) in order to engage with the various pathology organisations and societies to discuss issues such as terminology.

Thank you for these contact details. NEHTA will be in touch with the PAC as soon as possible.

2.2 Readers Guide

No specific comments were received.

2.3 Purpose and Scope

No specific comments were received.

2.4 Business Architecture

2.4.1 Queensland Health Commentary

QH-1 The BA is missing a state diagram for a pathology report

Thank you for pointing this error out. This will be included in any future release of the Business Architecture material.

QH-2 The BA should clearly define and consolidate a set of business requirements

NEHTA intends to offer the Business Requirements as an inclusion within one of the initial documents and to enhance their content by ensuring that all of the business requirements are captured from the industry.

2.5 Information Architecture

No specific comments were received.

2.6 Technical Architecture

No specific comments were received.

2.7 End Point Specification

2.7.1 Queensland Health Commentary

QH-3	<p>The web service communication model is focused on an extension of the current “point-to-point” paradigm.</p> <p>NEHTA is essentially replacing the current communication vendor products and their technology with web services.</p> <p>NEHTA need to address the question of what is the capacity of the industry to support web services.</p>
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This comment is being further explored. Further information will be provided as it is developed.

QH-4	<p>With point-to-point communication, information is not accessible electronically outside the sender and receiver.</p> <p>The NEHTA model for sharing of information as the patient moves between health services relies on the establishment of an individual electronic health record (IEHR) – a concept that is still to be agreed in principle, design and funding.</p> <p>Other countries and QH (for radiology images) are examining document registry/ repository concepts and federated models, as pragmatic first steps to more effective information sharing.</p>
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No comment required.

QH-5	<p>The communication model is reliant on the establishment of several NEHTA supported services in particular the SIL, UHI and NASH. No timeframe is given. The SIL has had less public exposure than the other services. In the absence of these services the current unacceptable model of proprietary point-to-point communication is recommended. There is no discussion of possible transition strategies or pragmatic approaches to support improved communication.</p>
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The suggested transition strategies have been explored internally. This will need to be socialised with a group of contributors to further its development moving forward.

QH-6	<p>NEHTA need to explore how the problems associated with interoperability between private sector communication services and the communication layer will be considered.</p>
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Unfortunately we are unclear as to what this question is asking. NEHTA will contact QH separately to fully understand this question.

QH-7	<p>NEHTA should also confirm whether the web services components will support both a federated and national information sharing initiative.</p>
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Unfortunately we are unclear as to what this question is asking. NEHTA will contact QH separately to fully understand this question.

The Web services components are specified independent of any particular deployment architecture. Therefore they can be federated or centralised.

If you think there are specific issues please let us know what they are and why they would prevent the services from operating in a federated model.

Results Reporting Feedback and Responses

QH-8 The model outlined in Scenario 2 (receiver not connected permanently to the internet) recognises the need for asynchronous models of communication in healthcare.

Other open communication models tackle this problem in different ways such as via a recipient notification of result availability, as touched on in the third NETHA model.

No response required.

QH-9 The use case descriptions suggest that the pathology provider can manage the locator service information in the absence of the SIL.

This is an implied fourth model. Feedback from the pathology industry suggests that most pathology services do not wish to be communication vendors (hence their ready willingness to engage commercial messaging services).

QH likewise has contracted this work to external messaging providers. To manage this information locally would be a significant effort.

Although pathology providers can manage the SIL themselves, they do not have to. Pathology providers can contract the operation of their SIL to external messaging providers. It is expected that this will be the default model used when an external messaging provider is being used.

QH-10 It should be noted that the range of models for implementation and how these are tied together into a coherent architecture is not clear. For example, the key role of infrastructure providers in any model of communication in health is not plainly described in these documents.

In fact one of the business requirements states that no intermediaries are desired. While this is stated and accepted at face value, this is not achievable, and it is acknowledged not to be the case in current practice.

While such a requirement may be a desire of the pathology industry, it is not practical in a world where pathology is only one of many communication types.

There is little or no consideration as to how the proposed architecture would work with the delivery and exchange of other health communication (radiology reports, discharge summaries, referrals, requests and so on).

The pathology package has been designed to support different deployment models, including the use of intermediaries. Support for intermediaries was the prime driver for the use of sealed reports. The Technical Architecture document outlines several scenarios that involve intermediaries. Further refinement of these scenarios is outside the scope of the Technical Architecture. This refinement should be done in conjunction with the actual intermediaries involved.

The services defined in the pathology package are designed for pathology. Specific services will be defined to support the other types of health exchange (e.g. discharge summary, referrals) and will be included as part of these programs of work.

2.7.2 RCPA Commentary

RCPA-3 In the End Point Specification (Section 5.3 Report Instance, it is considered that “from Individual” would usually be “from Organisation” in the case of Pathology Reports.

When the Draft Pathology Result Reporting Package was first published, it contained a superseded version of the Endpoint Specification, we apologise for any inconvenience that this has caused.

The correct version is now published on the NEHTA website. This version does not contain Section 5.3 - Report Instance. Instead, the section which defines how to specify the meta-data for a report instance is now labelled section 6.2.2. Sub-section 6.2.2.3 specifies that the sender of the report must be identified, using a URI which follows the NEHTA scheme for identifiers.

It indicates that the URI may be the HPI-O for the pathology laboratory that is sending the report. Sub-section 6.2.2.5 specifies that the origin field is used to identify the person responsible for sending the report. This field is defined as optional and therefore may be omitted from the meta-data.

2.8 Interchange Format

2.8.1 RCPA Commentary

RCPA-4 In the document mapping the SDT to HL7V2, the reason for the statement that ORU^R01 messages ‘will transform’ to OUL^R21 is not clear as this is optional in the standard.

The OUL^R21 (Unsolicited pathology observation) message was introduced in HL7 v2.4 (see HL7 v2.4 Chapter 7 for message definition). It contains 3 new segments (see HL7 v2.4 Chapter 13 for definitions of the segments):

- SAC – specimen and container details
- TCD – test code details
- SID – substance identifier

AS 4700.2 contains the statement “Use of the new messages is encouraged for laboratories that require to use and store information about the specimen and its containers, the test

code details and details of the reagents used to carry out the tests. For laboratories that do not require this information, it is acceptable for them to use the order and response messages as defined for medical imaging.”

AS4700.2 only implements the SID and TCD segments, it does not implement the SAC segment. The NEHTA interchange format does not include the TCD or SID segment.

The NEHTA interchange format also does not implement the SAC segment, because it was not implemented within the AS4700.2 Implementation Guide.

NEHTA is recommending use of the OUL^R21 message in accordance with the recommendation contained in AS4700.2 but acknowledging that, without use of the SAC, TCD or SID segments, if an organisation chose to implement the NEHTA interchange format into an ORU^R01 message instead – such a message would essentially be identical to a NEHTA compliant OUL^R21 message. However downstream systems may end up with confusion related as to how to process the ORU^R01 as a Pathology or as a Radiology message.

Having said this however, there may be a valid use case for the NEHTA interchange format to include the SAC segment. This is to be discussed further with Standards Australia over the coming period, and may make the current statements in the Interchange Format redundant.

2.8.2 Queensland Health Commentary

QH-11 Standards Australia has published an implementation guide for the AS4700.2 (2007). This NEHTA documentation references a superseded 2002 version.

When the interchange document was drafted this was the most current version published on the Standards Australia website. As this has now been updated we will endeavour to update references to this document.

Results Reporting Feedback and Responses

QH-12 IHE (Australia) and HL7 (Australia) have developed an integration profile for pathology messaging which was used in the 2008 Australian Connectathon and Interoperability Showcase and which further supports standardisation of HL7 message usage based on Australian standards, and provides a direction for harmonisation of Australian implementations of HL7 result messaging with that used in the international profiles. Also demonstrated was the IHE Cross Enterprise Document Sharing profile with a specific focus on the conversion of current HL7 lab messages to HL7 CDA and management in a longitudinal record (document repository) service.

NEHTA makes no reference to IHE or these local initiatives. It is important to note that the IHE profile for health information exchange has been adopted and is now being implemented in several other comparable countries and appears to meet the implicit requirements identified in the pathology package.

This document is a straight interchange mapping exercise between the NEHTA Structured Document Template and the Australian Standard AS4700.2.

Discussions of local initiatives are outside the scope of this document.

NEHTA acknowledges IHE work both locally and abroad. Discussions are underway to determine where IHE fits into the work being completed through NEHTA.

QH-13 It is not clear whether the treatment of acknowledgement messages is compliant with that required by AS4700.2.

The concept of message and application level acknowledgements is not clearly outlined in this document. The information architecture refers to the 'report processed acknowledgement'.

To the non technical reader it would be difficult to comprehend to what extent acknowledgments are being handled by the web services infrastructure and what is being handled by the HL7 message payload.

NEHTA will further investigate and amend the material where necessary. It is agreed that parts of the material developed through the e-Pathology Program need to be made clear to non-technical readers.

QH-14 Discounting the move to HL7 CDA as an interchange format has not been justified, especially when considering NEHTA's commitment to the use of more complex and structured reporting.

Accepting that this work essentially concerns the replacement of existing messaging methods, continuation of the HL7 version 2 model is appropriate, however this will not support some models of long term health record exchange that are document based.

Moving to beyond HL7 v2.x is definitely part of the strategy. HL7 Clinical Document Architecture (CDA) has been selected as the goal state. This needs to be better described in the e-Pathology material going forward.

QH-15 Backwards compatibility is a principle that is also not discussed.

Thank you for your suggestion. We will endeavour to include this within the material moving forward.

QH-16 The method of creating and standardising the various identifiers and instance identifiers is not stated. Some of the examples refer to OIDs; however Australia lacks a comprehensive system for managing OIDs in healthcare.

It is important to note that this is not to deny the value of this approach, but rather to highlight the need for their use to be carefully considered.

There is a need for a comprehensive system for managing OIDs in healthcare and this has been raised within NEHTA.

This issue may require further understanding to develop a position on OIDs.

Information regarding OIDs will be included in future e-Pathology material.

QH-17 Many code and reference sets are 'To Be Advised' (TBA). When is this likely to be completed?

The National Clinical Terminology Service (NCTS) is currently developing policies for managing CodedText / CodeableText data elements published in the NEHTA data/content specifications.

In subsequent terminology and specification releases, more information on the source terminology for the value domains will be provided. Where the value domain is noted as 'To Be Advised' (TBA), NEHTA recommends that implementers continue to use their current local codes that comply with AS4700.2.

NEHTA will work with Standards Australia, HL7 Australia, and stakeholders to determine the long-term approach to these value domains.

QH-18 The key terminology for Result Observation name is TBA – potentially LOINC.
NEHTA needs to specify the intended reference set. It should be noted that LOINC lacks hierarchy which supports the grouping of like tests, which may only differ due to a different methodology.
Despite considerable input from industry, the discussion of terminology ignores the work done by Standards Australia (AusPath) to overcome some of the LOINC deficiencies.

The 'Pathology Terminology Release – 20080829' did not comment on LOINC harmonisation as the data element 'Observable Name' was not within scope for this release (reason described below). This is the only data element described in the Structured Document Template – Pathology Results Reporting (SDT-PRR) that is dependent on the representation of an observable. As SNOMED CT, Australia's preferred clinical terminology, is currently inadequate to represent observable entities, LOINC codes could potentially be used to populate this data element.

The development of a reference set for the 'Observable Name' data element is pending due to the re-modelling of the Observable Entity Hierarchy within SNOMED CT. This work is being progressed by the International Health Terminology Standards Development Organisation (IHTSDO), the administrator of SNOMED CT. This remodelling exercise is likely to be completed next year.

Until the re-modelling has taken place, which then allows a terminology reference set to be developed, NEHTA recommends that for this data element, implementers use their current local codes that comply with AS4700.2. It is acknowledged that their local codes set may have some association to LOINC (e.g. via mapping etc). The IHTSDO is working with other standards development organisations to harmonise international standards. Subsequent Pathology Terminology releases will provide more information with regards to the interactions of SNOMED CT and LOINC.

QH-19 While supporting the use of SNOMED CT as a core health terminology, its use in laboratory related information models as a standard would place Australia amongst the first internationally to go down that path. As a result additional care and consultation is required to ensure that it is fit for purpose.

SNOMED Clinical Terms® (SNOMED CT) has been endorsed by the Australian Health Ministers Advisory Council (AHMAC) as the preferred solution for the core clinical reference terminology. Australia's migration towards SNOMED CT is also aligned with the endorsement provided by the World Association of Societies of Pathology and Laboratory Medicine (WASPaLM) in 2000, that SNOMED and its subsequent versions including SNOMED CT is the preferred clinical terminology for coding in pathology laboratories worldwide.

World Association of Societies of Pathology and Laboratory Medicine, 2000 [WASP2000], International Pathology Organization endorses SNOMED® As Preferred Reference Language for Laboratory Clinicians. <http://www.waspalm.org/pdf/snomed.pdf> <<http://www.waspalm.org/pdf/snomed.pdf>> (Accessed 9 October 2008)

QH-20 It is difficult to see how the NEHTA model uses "existing" identifiers and security protocols.

This comment has been taken on board and will be addressed in future e-Pathology material.

Results Reporting Feedback and Responses

QH-21 A detailed analysis of the proposed HL7 message content is needed with mapping to the current message design.

An area which appears to be an omission is the lack of a “rendered text” segment which allows for the laboratory to provide a rendered report for display to the reader.

Such a requirement is also embodied in the HL7 CDA. There are strong professional and safety reasons to support this business requirement.

The Structured Document Template does allow for Rendered text. DE-11019 – Report is for this purpose.

CDA allows for the use of Style Sheets to control data display also.

There are datatypes that can be used in OBX segments in HL7 V2.x suitable for encapsulated data, HTML etc.

2.8.3 AHML Commentary

AHML-11 What do the comments on page 7 of the Interchange format mean? ****There is no appropriate mapping to the TCD or SID segments therefore these are not included in this document****

It means that none of the data elements contained in the NEHTA Pathology SDT are mapped into these segments. Therefore, no tables for these data elements were included.

AHML-12 In the segment tables in the Interchange Format document there is no detail on length/optionality/cardinality

A number of questions have been raised about the appropriateness of the format and contents of the Interchange Format document, and its relationship to the AS4700.2 standard.

This is an issue that we hope to resolve over the coming months. It would be helpful to meet with AHML to discuss their opinion about what the NEHTA Interchange Format and Implementation Guide should contain. As a guide the fallback was to gather this information from the AS4700.2 standard.

AHML-13 Comments in these tables mention things like 'Must contain an identifier which will enable the receiving system to recognise the sender of the report', yet there are no details on how to do this

Details on implementation are to be covered in the Implementation Guide, which will be published with future e-Pathology package material.

AHML-14 Another comment stating 'Requires mapping to HL7 sex codes' so what does this mean are we suppose to use NEHTA or HL7 codes?

NEHTA is recommending that codes for Sex are drawn from SNOMED CT for use in Clinical applications. However the HL7 standard states that you must use a value from a defined HL7 table for sex codes. Therefore in a HL7 v2.4 message you would map the SNOMED CT code or a local code to the prescribed HL7 table for use.

AHML-15 PVI-2 & many others comment 'Values to be determined' when/how can this be implemented when it's not complete?

This means that at the time of authoring it could not be clearly articulated as how to place SNOMED CT information in the present structure. This and other issues need to be raised with Standards Australia. This is currently being progressed.

AHML-16 Have the data elements which 'can't be mapped to HL7' been taken to IT-14-6-5 for clarification? If they are not in HL7 then we may need to take them to HL7 International for discussion about inclusion?

NEHTA and Standards Australia are currently looking at how to proceed with this.

AHML-17 No year on the AS4700.1 reference

This will be corrected.

AHML-18 **The HB262 referenced is 2004, yet there is a 2008 revision**

When the interchange document was drafted this was the most current version published on the Standards Australia website, in fact the website link below still does not bear the 2008 version. The HB262-2008 version was published in May 2008.

<http://www.e-healthstandards.org.au/drafts.asp?area=publications>

However this will be corrected.

AHML-19 **Who did the mapping between the structured document and the HL7 messaging? This should have been done in collaboration with IT-14-6-5, there are some elements which are stated as do not map to HL7, when they do and if that is the case then all the mapping should be reviewed**

A meeting was held between NEHTA and IT 14-6-5 in December 2007 to kick off this process. Mapping work was then undertaken by Gillogley Services as stated in the background to the document (Section 1.1). That mapping has been reviewed by limited staff members within NEHTA. This means that for release 1 of the pathology package a comprehensive review of this document has not been performed.

The inadequacy of this process has been recognised by NEHTA, and will be documented in the "Lessons Learned" document to be publicly released as part of this process. It is intended to still include the Interchange Format document in release 1 of the pathology package but to preface it with statements that it is not intended to be implemented at this stage and is being released so that a comprehensive consultation process can take place to ensure that the Interchange Format published in release 2 of the pathology package (currently scheduled for May 2009) will be fit for purpose. For this reason, the planned accompanying Implementation Guide is no longer to be published with release 1 of the package, but will be published with release 2 so that this input can be incorporated into the guide.

It is intended that meetings will occur with IT-14-6-5 and, if necessary, HL7 International on these topics during this time.

AHML-20 **Why HL7 2.4? You are not proposing to utilise the new features of 2.4 so why move if only changing the message name and version number?**

The primary purpose for the suggestion of v2.4 is not to force implementers to "move". The primary purpose is to settle on a standard that can be used by all implementers in Australia to standardise pathology messaging. Whatever standard was chosen would therefore require some implementers to "move" and other implementers would not be required to change the version implemented (although they may still be required to change some aspects of their implementation to conform).

In deciding which standard to settle on, NEHTA has taken the following issues into consideration:

- No implementers should have to move backwards in order to comply;
- The standard must conform with NEHTA's policy published in "An evaluation of standards supporting interoperability in e-health";
- The standard must not force implementers to operate outside of guidelines of their accreditation bodies.

NEHTA believes, that in the pathology domain, HL7 v2.4 is the standard that best meets all of these criteria, for the following reasons:

- As stated on p.35 of the Purpose and Scope Statement : "Version 2.4 of HL7 is the most recent Australian Standard stated for use in AS4700.2 and aligns with statements in the NPAAC guidelines [NPACC2007]"
Alignment with NPACC guide G6.1:
"G6.1 Electronic communication of requests and reports should comply with protocols set out in the Standards Australia publications AS4700.2-2004 and HB262-2002 and their subsequent revisions."
- There are some existing pathology implementations in Australia utilising HL7 v2.4 and AS4700.2-2007.

Results Reporting Feedback and Responses

AHML-21 Specimen Identifier is mentioned to not map to HL7, yet there is a new segment in the 2.4 OUL message, SAC which has a Accession Identifier (SAC-2) - Why is the SAC segment not included in the message structure?

The SAC segment was not used because it has not been included in the AS4700.2-2007 Implementation Guide for the OUL^R21 message. This decision will be revisited over the next couple of months.

AHML-22 In the Structured Document Template the Specimen Collection Setting states it maps to OBR-11, this should be OBR-10, there could be more like this but I didn't look at them all

The mapping of specimen collection setting is in our current issues list as we agree that it is not a map to OBR-11. However, we also question whether it is a good map to OBR-10. We would like to discuss this issue further:

2.9 Terminology

2.9.1 AHML Commentary

AHML-23 Where are the SNOMED-CT reference sets? And documentation on how to implement these within a message?

The clinical terminology component of the Pathology Package is available directly from NEHTA's secure site (<https://nehta.org.au/aht/>) or via the NEHTA website. Access to this secure site is restricted to those holding SNOMED CT license agreements managed by NEHTA. To apply for the free licenses, please register at <https://nehta.org.au/aht>

From the AHT site please navigate to: [Home] -> [Downloads] -> [Pathology Data Specifications and Terminology]. Here you will find all terminology artefacts included in this release.

The Reference Sets themselves are included in the data release. You will need to refer to the supporting material provided on how to view these.

These artefacts include:

- Pathology Terminology Cover Note;
- Pathology Terminology Release Note;
- Pathology Terminology Approach Document;
- Pathology Terminology File (xls file);
- SCT-AU Reference Set Implementation Guide
- SCT-AU Terminology Viewer; and
- SCT-AU Distribution file.

The terminology associated with this Pathology Terminology release is provided as a Microsoft Excel® file and also as terminology reference sets using the SCT-AU Terminology Viewer. The contents of the reference sets are best viewed using the SCT-AU Terminology Viewer that is provided. The data bundled with the viewer contains SNOMED CT identifiers and therefore requires interested stakeholders to have licensed SNOMED CT through NEHTA prior to obtaining it for review. The SCT-AU distribution File (draft 20081031) associated with this release is based on the Jan 2008 SNOMED CT International release.

This distribution file contains:

- Three data files:
 - Concepts
 - Descriptions
 - Relationships
- UK Language Sub Set
- ICD9 Mapping Files

Additional structures identifying content relevant to Australia, including the Pathology Reference Sets.

For information on implementing reference sets within an information system please refer to the SCT-AU Reference Set Implementation Guide. NEHTA is currently developing a strategy on how to implement the SNOMED-CT reference sets within various message types and this will be covered in the implementation guide to be released with v2 of the pathology package.

2.9.2 Queensland Health Commentary

QH-22 Would NEHTA be willing to provide the mapping of the QH Pathology file to SNOMED CT (given the mapping was done to develop the reference sets to support this package), if this was to be requested?
How could this be provided?

The current mapping of Queensland Health pathology tests to SNOMED CT can readily be provided as an Excel file. Please note that the test mappings would need to be validated by Queensland Health before use in clinical systems. NEHTA does not consider the mappings fit for clinical use.

NEHTA will shortly be releasing the SCT-AU Pathology Mapping Tool which will allow Queensland Health to easily extend the mappings and additionally provides a mechanism to provide feedback to NEHTA.

QH-23 The SCT-AU release will need to be communicated so as to enable local management. Is the process for this going to be via the NEHTA Secure Website?

The SNOMED CT Australian Release (SCT-AU) is provided via the Australian Health Terminologies (AHT) secure website. News of releases on the AHT site is currently provided by the RSS feed on the main NEHTA site.

NCTS Service Management will be providing a subscription to a Terminology Services Newsletter that will be distributed to our Licensees on a quarterly basis. This will enable us to provide our licensees and other interested parties information about the work programs that are underway within Terminology Services and the various teams that are making this happen. A subscription process will enable licensees to subscribe via the secure website to the Newsletter and non license holders may also subscribe by emailing terminologies@nehta.gov.au

We will also be providing product information after every release notifying our licensees of important information about the release. This will also follow the subscription method highlighted above for both Licence and non licence holders

[SCT-AU is the Australian release of SNOMED CT which includes the International Release along with all Australian content as it is developed, including Reference Sets and Australian documentation. We will be providing more information about the structure and timing of these releases shortly.]

QH-24 The 2nd paragraph refers to 'A specialised in-house terminology software tool' What is this tool and is it available? Or, is this referring to NEHTA's terminology tool that they have procured and commercially licensed for NEHTA use only?

NEHTA is investing in the development of a Terminology Development Environment and associated tool set. This will be an ongoing effort and initial development has been targeted at supporting the NEHTA Terminology work program. Some components of this tool currently have licensing restrictions that prevent us from making this toolset broadly available.

The end objective is to provide an open and collaborative Terminology Development environment for the Australian e-health community. We are working closely with the IHTSDO and other member countries such as the NHS UK to determine the shape of this and will inform the Australian community as things develop. We are going to work along open source lines so that we are able to make toolsets broadly available.

QH-25 The 3rd paragraph states that there is a single list of test names, although the data elements for 'Request Test Name' and 'Result Test Name' reference 2 different value domains. Please clarify.

Currently the concepts contained in the reference sets for 'Request Test Name' and 'Result Test Name' are equivalent. The concepts in these reference set were derived from the Australian Reference List by identifying the baseline concept (i.e. a test without additional qualifying information). Despite the content of these reference sets being the same at this point in time, they have been kept separate as it is anticipated that these reference sets may evolve independently depending on stakeholder feedback.

Results Reporting Feedback and Responses

2.10 Structured Document Template

2.10.1 RCPA Commentary

RCPA-5 In regard to Pathology Episode (Result report model) it is possible to have no requesting provider. It should probably be mandatory to have a requester.

Agreed. This change will be applied to the document.

RCPA-6 For Pathology result report details, a request order identifier is noted as mandatory but this will be hard to conform to as the result reporting package doesn't take into account orders as yet. On the other hand, the laboratory request identifier is classed as desirable but should perhaps be mandatory.

Requester Order Identifier changed to 'Desirable'. The following paragraph is included with the notes for this data element. "This data element has been flagged as 'desirable' at this stage in recognition of the fact that very few electronic ordering systems exist. If electronic ordering is in place then the requester order identifier should be returned in the pathology result report.

Laboratory request identifier has been changed to 'Essential'."

RCPA-7 The Structured Document Template (SDT) could be presented more clearly. For example the relationships in the information model would be more easily discerned if an electronic format could be published that allows the SDT to be explored as a tree structure.

This comment has been received from a number of people. In the past, NEHTA has published data specifications on its website and has provided both a PDF format and an XML format. Publishing the file as an XML format using current tools is quite a long and difficult process and is therefore usually done once the document is in its final form (e.g. once the review period is over and agreed changes have been made).

However, due to the number of requests we have had for

producing an electronic navigable version during the comment period, we are currently investigating tools and means of achieving this for the next "for comment" release of package documents.

RCPA-8 There was no mention of a data element for units of measure in the SDT. Other documents indicate that the Data Value element is a compound structure including units of measure, but this should be explicit in the SDT.

Units are contained within the "Quantity" data type and any other data type that embeds a quantity (Quantity Range, Ratio). The data type legend in Section 4.3 of the SDT defines a quantity data type as containing magnitude, units and precision components.

There are only 2 elements in the pathology SDT that are bound to any of these data types – being the Result Observable Value and the Result Observable Reference Range.

We will modify the "Notes" component of these data elements to explicitly make reference to all components of the bound data types. We are also introducing some paragraphs before the data types legend to explain the compound nature of the data types and to point readers to the document, which explains each data type in detail.

2.10.2 Dr Ben Connell's Commentary

Due to the numerous specific issues raised in Dr Connell's commentary, this information is provided in a different format.

Page	Location	Comment	Proposed Resolution
7	Section I.1, Paragraph 1	This document forms part of a suite of data specifications that NEHTA has developed for the Australian health informatics and clinical communities. Included within the suite are: <i>Pathology suite or all suites - i.e. pathology, discharge summaries etc.?</i>	Section I of the document has been completely revised to deal with these issues and other issues raised from other parties.
7	Section I.1 lettered list	a. specifications that outline ? data elements designed for storage and capture of clinical information for specific domains, b. structured document templates for organising these data elements to form clinical communications ? for a given purpose and c. interchange formats that bind the structured document template to particular messaging formats. <i>I have found myself in the next few pages trying to see where this list is referred to again</i>	
7	Section I.1, paragraph 3	The documents specifications used within the pathology results reporting community form a 'package' which, as delivered by NEHTA, is are intended to describe how NEHTA's specifications are to be adopted and used in conjunction with one another and to provide enough supporting material to enable inform adoption and implementation across the e-health community.	
7	Section I.1, paragraph 4	These documents, together with terminologies, are provided as specifications for the content structure of a clinical information exchange between a pathology laboratory and an authorised clinician; i.e. a Pathology Result Report. <i>I have suggested this change because I interpret content as meaning what the result actually is. For example appendicitis. The aim is more about how that report saying the result is appendicitis is structured. Perhaps too pedantic.</i>	
7	Section I.1, paragraph 5	This document is outlines the Structured Document Template - Pathology Results Report specification. It describes the data elements proposed for use in communicating pathology results. <i>I am trying to work out if what you are saying is that this document addresses point b. above</i>	
7	Section I.1, paragraph 6	The Interchange Format specification describes how HL7 can be used to encode and send ? pathology results data elements between a sender and a recipient. <i>Is this saying the same as point b in the above?</i>	
7	Section I.1, paragraph 7	Together they form one component of a solution proposed for the pathology result reporting community. Other components such as the infrastructure for electronic messaging are covered in alternate specifications. <i>Perhaps what is meant by infrastructure is a bit vague? Maybe it should be qualified</i>	

Results Reporting Feedback and Responses

Page	Location	Comment	Proposed Resolution
8	Section 1.3, bullet 1	Report from a laboratory to the requesting clinician, whether they be in general practice the community or hospital setting. <i>since there are many non hospital doctors other than GPs who require pathology results (for example specialist in the community, district nurses etc, etc)</i>	Section 1 of the document has been completely revised to deal with these issues and other issues raised from other parties.
9	Section 1.4.1, bullet at top of page 9	improve interoperability of information exchanged between health organisations; <i>Perhaps expand what this word means?</i>	
9	1.4.2, Heading	Clinical Data Specifications <i>Is this one of those 3 items (a, b or c) mentioned at the start of the introduction or is it unrelated?</i>	
9	1.4.2, Paragraph 1	...Data elements on their own are simply granular pieces of information... <i>Would be worth describing what this means. It is mentioned in other documents too. I don't understand what the word means in this context</i>	
9	Section 1.4.3, Paragraph 1	The Structured Document Template outlines the allowable content of the information to be exchanged for in a Pathology Result Report...	
13	Table 1 Value Domain Examples	<i>this is a very helpful table. Is it possible to give examples for section and data group the same way they have been given for element and value domain.</i>	
14	Section 1.7.2, Paragraph 1	The Structured Document Template - Pathology Results Report should not form the basis of a referral . There ... <i>I'm not sure what is meant by this. Is it saying that the report should not be used as the pathology request? If so, I'm not sure how this could happen.</i>	
15	Section 2, Paragraph 1	The Use Cases described in this section are used in conjunction with the Structured Document Template - Pathology Results Report (SDT-PRR) <i>Isn't that this document? I don't really understand what this is saying.</i>	This sentence has been changed to make sense.
15	Section 2, Paragraph 1	There are three types of acknowledgement associated with the receipt of a Pathology Results Report: <ul style="list-style-type: none">• Message receipt acknowledgement <i>Would be worth clarifying what the difference is between this point and the last one on this list. Is this saying where the result being received is acknowledged by someone or something else other than the system and/or clinician. I can't think of who or what else would acknowledge receipt other than the system or clinician.</i>	The 2 acknowledgements are not the same - the first one really is analogous to a letter arriving in a letterbox at the specified address; the last one means that somebody has retrieved the letter from the letterbox, opened it up and read it. This clarification has been made in the document.
18	2.4.1, Aliases	Should include electronic medical record (EMR)	Change made

Page	Location	Comment	Proposed Resolution
18	2.4.4, Aliases	<i>Although the purpose and scope document says that only GPs will be included. Also, I thought only community clinicians were included (as per the purpose and scope document). They were a bit vague about what a community clinician was but I interpret that as excluding Hospital doctors</i>	GPs as receivers of Pathology Results are in scope for Release 1. Many different organisations can request pathology and require a copy of the report to be sent to a GP. A Community Clinician includes any clinician working in the non-acute sector.
23	3.4.4, UML	small font, difficult to read	These are being resized to address this issue.
27	4.1, Title	Obligation Legend <i>Perhaps add a few more examples since some don't have examples. Very helpful where there are examples.</i>	Obligation legend has been checked and examples added to every item in the legend.
27	4.1, Essential	e.g. Alert without an Alert description does not make sense. <i>What does this last sentence mean</i>	
27	4.1, Optional	Indicates that the data item may be supplied if required within a context and if the data is available, but it is not necessary for the data entry to make sense. <i>I don't understand this last bit of the sentence. Giving an example would be really helpful here. Why would information be inputted if it didn't make sense?</i>	
27	4.2, Packages	This seems a bit out of context in this list.	Correct. It has been removed
27	Footnote	See 1.6 for explanation <i>electronic link would be helpful</i>	Electronic link added
28	4.3, Text	... Sometimes referred to as free text. <i>Good that this is added in here since most people know what free text is. Perhaps some of the other data types have a layman term that would help explain them.</i>	This level of detail has been added to each data type
28	4.3, CodedText CodeableText	<i>I'm not sure if I understand the difference between these two. Could they be explained more? Would it be possible to give examples.</i>	Clarification of the difference has been made in the document.
29	4.3, Unique Identifier	<i>For example, patient hospital identification number</i>	Example/s added to the document
30	Dynamic	<i>Not clear to me what the difference between this and free text is. Example would be good</i>	Example/s added to the document
30	Set	<i>Example would be good</i>	Example/s added to the document
30	Participant	...and organisations who are operating within a defined healthcare domain ... <i>What does this mean? Perhaps add to glossary earlier in the document.</i>	Healthcare domain has been added to the glossary

Results Reporting Feedback and Responses

Page	Location	Comment	Proposed Resolution
30	Footnote	For further explanation ... <i>Would be good to add a few extra explanations in the spots I have indicated since this will allow the reader to have sufficient understanding of the different datatypes without going to the extra document.</i>	Extra explanations have been added which also include a link to the document.
31	Multiple occurrence	<i>of what? Not sure what this means. May become clearer later.</i>	This has been clarified by changes to the obligations table with supporting examples
31	Externally sourced ...	<i>Examples would be very helpful for all of these.</i>	Removed, as not applicable to this document
33	5 Data hierarchy, para 1	Spelling mistake - locigcal	Fixed
33	DH - Pathology report identifier	<i>As a clinican, the quickest way to get a result is to give the "lab reference no". I assume that one of these two represents this.</i>	The identifiers referred to in the header are really internal identifiers for document management systems. The Lab Reference Numbers (there is one for each request and one for each result) are contained within the report detail.
33	DH - Subject of Care	<i>Is this the patient? Would be worth clarifying this.</i>	New section 1.7 added "Terminology used in document" - discusses use of subject of care and relationship to patient. Synonymous names also added to data element page.
37	6.1, Pathology Result Report	Synonymous names - include pathology result	Added
38	6.1, Pathology Result Report	Conditions of Use - change results to result	This change has been made throughout the document.
39	6.2, Version Tracking	Notes paragraph 1 : ... when discrepancies between the documented contents and facts new findings are identified discovered. ... at the point of attestation ... <i>I haven't heard of this word before</i>	Suggested changes made to text. A section (1.7.2) has been included on attestation of documents and a link through to this section has been included.
40	6.2, Version Tracking	<i>Version Number - the only difference between version no and Path rpt instance identifier is the version no increments. Are there any other differences? The PRL will probably increment too although not a pre requisite.</i>	We will add a section on identifiers to beginning of document to attempt to clarify these sorts of questions.

Page	Location	Comment	Proposed Resolution
42	6.3, Pathology Report Instance Identifier	Notes : The value of this the pathology report identifier data element enables systems <i>Without this change is reads that the pathology report instance identifier provides the function of reminding that the report is for the same specimen</i>	Change made
42	6.3, Pathology Report Instance Identifier	It is recommended that the Pathology Results Report Instance Identifier value should be globally unique.The global uniqueness value of this Identifier can be achieved by concatenating the Pathology Report Identifier and Version Number. <i>I don't understand what concetenating means but I assume the uniqueness only occurs after these two numbers are combined. This sentence reads that the PRll is unique in its' own right.</i>	Sentence removed.
44	6.4, Pathology Report Identifier	Global uniqueness can be achieved through the use of a DCE UUID , or an Object Identifier (OID). <i>Many readers (myself included won't know what this stands for)</i>	Added to glossary
46	6.5,Version Number	Notes: The value of the Version Number is generated manually or automatically by algorithmic process, and is available for use within manual and/or an electronic system. <i>I assume that the version no's will be 1,2,3 etc or will they be much greater multi digit integers?</i>	They are intended to be 1, 2, 3 in messages, although they may be multi digit integers internally in documents before sending out.
50	6.7, DateTime Document Created	Notes: For a Pathology Results Report this may be defaulted to the Specimen Collected DateTime. <i>Frequently the specimen date/time will not be known. What happens then? I would have thought that the result time will always be known.</i>	The notes for this data element have been changed to read: The purpose of this data element is to convey information regarding the time and date in which a Pathology Result Report was created by the Laboratory Information System. As this time and date stays consistent across different versions of the document, it may be used by a document management system for sorting/ordering purposes. For a Pathology Result Report this may be defaulted to the Specimen Collected DateTime, DateTime Issued or DateTime Request Received, whichever best matches the business process of the individual pathology laboratory.

Results Reporting Feedback and Responses

Page	Location	Comment	Proposed Resolution
52	6.8, DateTime Issued	Notes: ..attested. <i>This word seems a bit vague. The authorisation time will be different to when it is attested.</i>	A section (1.7.2) has been included on attestation of documents and a link through to this section has been included.
53	6.9, Health Event Context	<i>an example would be good here</i>	We have attempted to put examples with the individual data elements contained within this data group. It is quite difficult to provide an example for the whole data group. We have had other feedback that this whole data group is a bit confusing and it would be helpful to discuss with reviewers so that we can attempt to provide clarification.
56	6.10, Subject of Care	Entity Identifier <i>The summary document used the more formal terminology for these. From memory it was UHL: provider (or something like this). Perhaps you could put this in brackets</i>	Change made
60	6.13, Facility	<i>In the purpose and scope document, the facility has a more formal name. Is "facility" in this document described in the purpose and scope document (my recollection is that it was). Would be good to use the same terminology.</i>	It should be. We'll check and amend where necessary.
-	Entity Identifiers	Questions as to why the document specifies two identifiers. This question recurs with other participants. Also surprise that HPI-I is not a "must". Are there plans to make it a must?	The point we are trying to make in the document is that the identifier must be capable of establishing the identity of the person described for the receiving system. HPI-Is etc. will take some time to roll out and therefore may not be available for all participants in initial stages. This is why it is a "should" at this stage. When 100% coverage is achieved with these identifiers it will become a "must".
-	Electronic Communication Details	<i>..electronic return message, delivery address - Is this obtained from the SIL? These terms introduced in the SIL but not referred to here. Is this because they are different?</i>	This is an implementation issue which still needs to be addressed and will be covered in subsequent releases.

Page	Location	Comment	Proposed Resolution
70	Request Detail	<i>Is this because the requester might add extra clinical details at the pathologist's request?</i>	The purpose of including "Request Detail" in a result report is to confirm the status and completion of the ordered tests back to the requesting system. This statement has been added to the Notes of the Request Detail data group.
8	I.3, Last bullet point	<ul style="list-style-type: none"> Report from a laboratory to a notification system or registry for notifiable or infectious disease. <i>My recollection of the purpose and scope document was that this was not included</i>	This is out of scope for this package and this has now been made clearer in the document.

2.10.3 Queensland Health Commentary

QH-26	It is not clear how the Structure Document Template relates to HL7 CDA and why this complete document model has not been referenced, mapped to or adopted.
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See the QH-28 for this response.

QH-27	The role and usage of the structured document templates is not clearly described. This stage of abstraction, documented in XML is not part of the common development path for HL7 v2.x messages. A mapping to HL7 CDA would be beneficial to check the validity of the document model produced.
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Movement beyond HL7 v2x interfaces is desired.

The Structured Document Template's role is to describe clinical information standards independent of any messaging format. Through the use of an interchange format mappings are made between the structured document template and a specific messaging format: i.e. HL7 v2.4 or CDA etc.

General	Throughout this document the terms patient, individual and subject of care are inconsistently used. Suggest alignment with the current Health Care Client Identification (HCCI) standard and the use of the term client.	"Subject of care" is NEHTA's preferred term. Will make this consistent throughout document.
	The name, address and electronic communication should be as per the HCCI standard. It is suggested that where there is reference to client demographic data that the document aligns with the HCCI.	We assume you mean the AS5017 standard. NEHTA's 'participant data group' is available as a separate document and does demonstrate alignment with this standard. This document has not yet been released because there are a number of items that NEHTA wishes to work through with SA to ensure satisfaction with the alignment.

Results Reporting Feedback and Responses

General	There is inconsistency in the naming of the 'Pathology Result Report' throughout the document. For example, 'Pathology Result Report', 'Pathology Results Report' and 'Pathology Report'. This needs to be corrected.	Thank you. This should be "Pathology Result Report" and will be made consistent throughout the document.
	The definitions throughout the data specifications require review. There is inconsistency in what is included or not included (for e.g. extraneous information that should be included in the notes), definitions that do not align with their names and some that are not definitions. Many of these are highlighted herein.	Responses to these issues are provided where highlighted individually in this document.
6.1 Pathology Result Report – Definition	The Definition section refers to a "unique requestor (who must be a healthcare provider – individual)" this should be a uniquely identified requestor rather than 'unique'. Question whether the information in brackets at this dot point means the provider must have a HPI-I?	Change made. Information in brackets means what it says. The obligation on healthcare providers to have an HPI-I has not been determined at this stage.
	The definition refers to a "unique patient" this should be uniquely identified patient.	Change made
	The 'Notes' section introduces an 'authorised clinician'. Does this need to be described in section 2.4 or be included as an 'Alias' in section 2.4.6?	An authorised clinician is defined in the note where it appears. It is not the same concept as in 2.4.6
6.3 Pathology Report Instance Identifier , p42	Inconsistent Report naming terms used – refer general comment above.	NEHTA is now making document headers consistent across all SDTs. This will therefore now be named Document Instance Identifier (with a synonymous name of Pathology Result Report Instance ID)
6.3 Pathology Report Instance Identifier – Notes	The Notes section states that "It is recommended that the Pathology Results Report Instance Identifier value should be globally unique". Suggest this 'must' be globally unique, rather than 'should' as per the requirement for the Pathology Report Identifier.	NEHTA is introducing a new ID – being the sending system ID. Together, the document instance identifier and the system ID will be globally unique. These notes are therefore to be redrafted.
6.5 Version Number – Notes	The Notes section states that "The Pathology Results Report Version Number value should be unique within each Pathology Results Report set". Suggest this 'must' be unique, rather than 'should'.	Change made.
6.5 Version Number – Conditions of Use	Suggest this description be in the singular.	Agreed – This will be changed.

<p>6.7 DateTime Document Created</p>	<p>Notes - 'may be defaulted to Specimen Collected DateTime'. It does not seem appropriate to default to this time, but rather to the DateTime Issued or DateTime Request Received.</p> <p>The DateTime Issued data element makes no reference to a default date or time.</p>	<p>We are making the following changes to clarify this element in the Note section:</p> <p>"The purpose of this data element is to convey information regarding the time and date in which a Pathology Result Report was created by the Laboratory Information System. As this time and date stays consistent across different versions of the document, it may be used by a document management system for sorting/ordering purposes.</p> <p>For a Pathology Result Report this may be defaulted to the Specimen Collected DateTime, DateTime Issued or DateTime Request Received, whichever best matches the business process of the individual pathology laboratory."</p> <p>A default for the DateTime Issued was not deemed to be helpful.</p>
<p>6.8 DateTime Issued – Definition</p>	<p>It seems most appropriate to keep the definition as simple as possible and use only one of the words 'attested' or 'authorised'.</p>	<p>Both words are used because of previous feedback that some people understood what attested meant, and some understood what authorised meant. We have received feedback that we need to define both of these things and this will be done within the notes section.</p>
<p>6.10 Subject of Care</p>	<p>It is not clear why the HCCI standard is not being used here?</p>	<p>See previous comments. The AS5017 standard is being used, but is being extended to represent the concept of a 'participant'. The AS5017 is for identification purposes only, not for participations. This is described in the (soon to be released) participant data group.</p>
<p>6.10 Subject of Care – Address</p>	<p>The condition states that "Must contain an address for the subject of care and the address type. Preference is for the normal residential address to be given. May contain postal addresses."What purpose is the address for? E.g. follow up, mailing, billing? This will determine the address information recorded.</p> <p>The address details should follow the HCCI standard, i.e. "...normal residential address..." is not a permissible value for the standard, this may be a value of residential permanent depending on the requirement.</p>	<p>We agree that the purpose and use of providing the information for each participant should be included. This will be added to the notes section.</p> <p>In a clinical document, address information is included generally for follow up as the primary purpose (with billing as the secondary purpose) – hence normal residential address is the preference.</p> <p>As stated previously, AS5017 is an identification standard – this has a different primary purpose and hence why NEHTA is complying with it, but not following it to the letter.</p>
<p>6.10 Subject of Care – Person-Name</p>	<p>The condition states "Must contain name details (family name and given names)". Again the HCCI standard should be followed, which includes the recording of a name usage type that would indicate the purpose of the name e.g. 'Preferred name, Medicare card name etc.</p>	<p>This is included in the participant data group documentation.</p>

Results Reporting Feedback and Responses

6.10 Subject of Care – Person Additional Demographic Data	The condition states that “Must contain the following details: Date of Birth- Sex” How are/will an estimated date of birth be handled?	This information is outlined in the participant data group documentation.
6.11 Facility detail - Definition	What is intending to be captured as part of the ‘context of attendance’?	Possibly not good wording. Care setting covers context – e.g. Whether they are in a Emergency Department, ICU, outpatient setting etc.
6.13 Facility – Entity Identifier	The condition states that “Must contain an identifier which will enable the receiving system to recognise the facility. Should contain the facility’s HPI-O if available”. What Identifier will be used in the absence of the HPI-O for all entities to understand?	Preference is for HPI-O, as the unambiguous representation. The alternative is as per current practices determined through negotiations between the endpoints.
6.15 Pathology Test Requester – Definition	The definition should describe what a Pathology Test Requester is and should not start with ‘In this context this is’. Suggest ‘The clinician who initiated...’	Change made.
6.15 Pathology Test Requester – Address	The condition states “Should contain an address” What address is to be recorded? Refer to previous comments in regards to address.	Good question – do we need it at all? Probably not as the purpose here would be to ensure pathology lab is able to clarify the request if they need to. Changed to “not required”
6.15 Pathology Test Requester – Electronic Communication Details	The condition states “Must contain an electronic return message, delivery message; and Must contain telephone contact details.” What phone number is to be recorded here? Refer to alignment with HCCI.	Wording to be changed to “Must contain telephone contact details that can be used by the pathology laboratory to contact the requester if required”. Previous comments re AS5017 also apply to AS4846. Purpose of this standard is also identification – purpose of this spec is clinical care.
6.15 Pathology Test Requester – Person Name	The condition states “Must contain name details.” What name is expected to be collected here? Refer to previous ‘Name’ comments. This data Group appears to be the same as 6.26 although the definitions are different there does not appear to be sufficient information to understand the purpose and difference.	Refer to previous name comments. The Pathology Test Requester is relevant at the Health Event Context level as it is often useful to know at the document metadata level as to who placed the request. More importantly this information is contextually placed at the Request Detail level. Difference is to be made more explicit in document.
6.16 Pathology Report To	Conditions for Address, Electronic Communication Details and Person Name, please see previous comments.	Purpose and use to be included in Notes section.
6.17 Pathology Episode – Definition	Unique requestor and unique patient, suggest this should state uniquely identified requestor and uniquely identified patient.	Changes made
6.19 Priority – Definition	Suggest revising the definition for clarity and to align with the data element being related to a request. Possible suggestion: ‘The level of precedence given to a pathology request.’	How about “The urgency associated with the timing need of the result report as determined by the requester.” Your definition associates it with the request, but does not clarify whose level of precedence it is.

<p>6.19 Priority – Notes</p>	<p>The Notes section refers to ‘...the routine turnaround time...’. This needs to be described. What is meant by ‘routine’?</p> <p>The Notes section also makes reference to ‘...a default value of ‘normal’ should be used.’ This needs to be described. If this is suggested as the default, it should be included in the examples.</p>	<p>This quote is not ours (although I have noticed that we failed to include the reference in our reference section – RCPA Chain of Information Custody Guidelines).</p> <p>Default changed to ‘routine’</p>
<p>6.19 Priority – Usage</p>	<p>The Conditions of Use states “...should be in keeping with the level of urgency of the situation...” What is an urgent situation? If this statement is included it would seem that more explanation is required as to what an ‘urgent situation’ is.</p> <p>The categories used in the examples should be described and perhaps be linked to turnaround time.</p>	<p>What is an urgent situation depends upon rules agreed in the health environment in which the request is made, and any agreement that is in place between the requester and the laboratory.</p> <p>Examples are just that – examples, the actual values for this data domain are yet to be defined.</p>
<p>6.20 DateTime Requested</p>	<p>Should the name of this data element and the definition specify it is a ‘test or ‘pathology intervention’ request?</p> <p>Should this data element specify that this may be automatically derived by a clinical information system?</p>	<p>A request could be many tests, and therefore many interventions. Therefore, current definition is valid</p> <p>In a result, you are simply reporting back the details in your system relating to the request. In the request however, (not yet specified) you may like to state that this may be automatically derived by a clinical information system.</p>
<p>6.21 Request Status</p>	<p>The definition for this data element is not defining what a request status is and should be revised. The additional information included in this definition that describes the purpose of this data element should be included elsewhere, possibly the notes section.</p> <p>The examples provided do not seem to be appropriate for a ‘Request Status’ or as the Synonymous Name suggests ‘Order Status’.</p>	<p>Change made.</p>
<p>6.22 Clinical Reason For Request</p>	<p>There is extraneous information included in this definition that should be included elsewhere. E.g. ‘The clinical reason should not include...’</p> <p>The 2nd paragraph of the definition states “The information can also indicate whether...” Suggest this is reworded to state ‘The information may indicate whether...’ This paragraph is not part of the definition and as such should be placed elsewhere.</p>	<p>Statement moved down to notes</p> <p>Reworded and moved down to notes</p>
<p>6.23 Related Problem Or Diagnosis – Definition</p>	<p>The definition states “A description of the problem/diagnosis pertaining to the subject of care which is relevant to the generation of the pathology investigation.” Suggest this is reworded to state ‘...which is deemed clinically relevant’.</p>	<p>Change made</p>

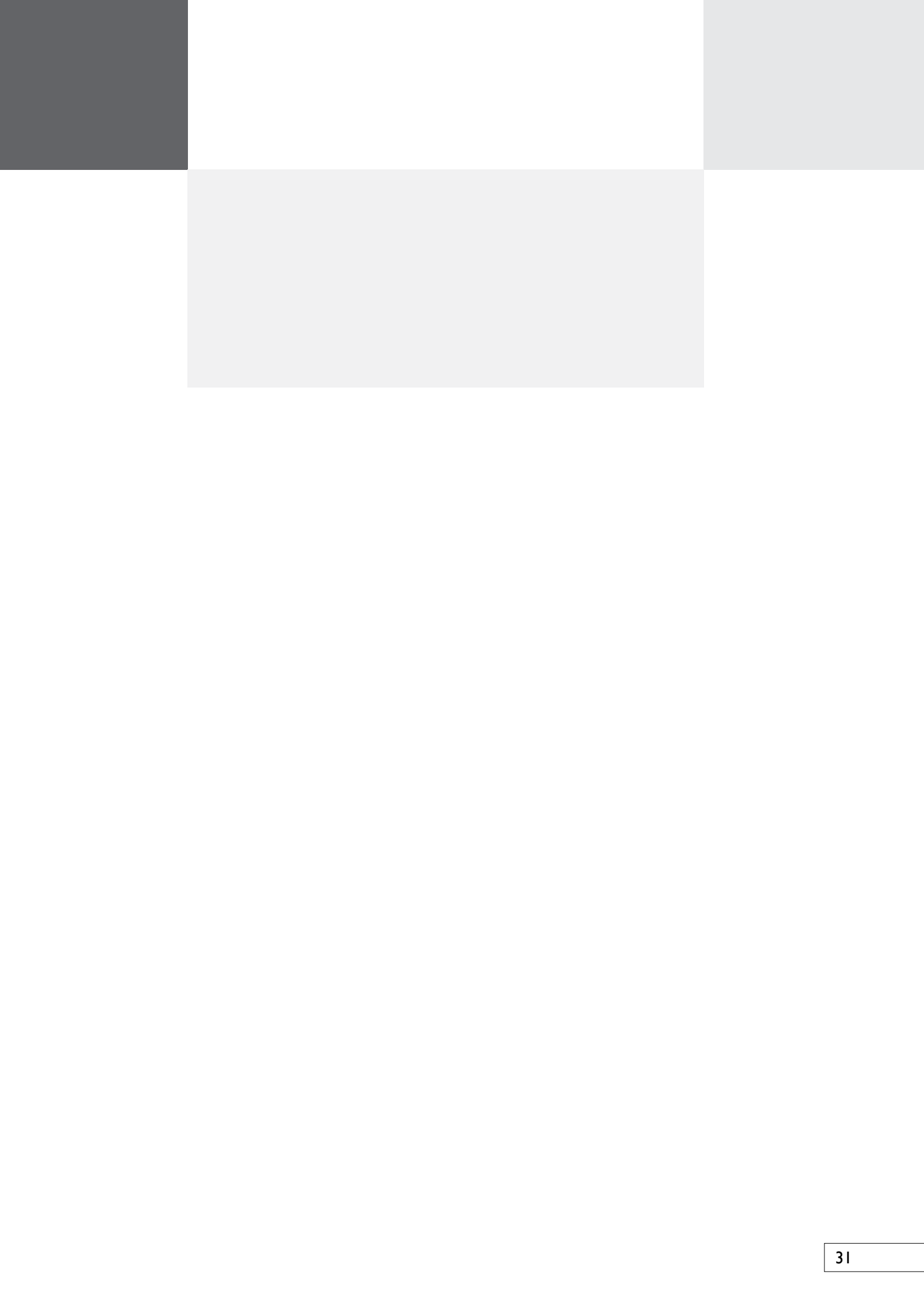
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6.23 Related Problem Or Diagnosis – Usage	As per comment above, the Conditions of Use refers to 'relevant' suggest 'clinically relevant'.	Change made
6.26 Pathology Test Requester – Definition	This definition is not a definition. Suggest removing the words 'In this context, this is'.	Change made
6.26 Pathology Test Requester	This data Group appears to be the same as 6.15 although the definitions are different there does not appear to be sufficient information to understand the purpose and difference. Conditions for Address, Electronic Communication Details and Person Name, please see previous comments	See 6.15 above for response
6.28 Specimen Detail – Definition	Suggest removing the word 'requesting' before clinician, as this seems redundant in the definition.	Change made
6.32 Specimen Identifier – Definition	The 2nd paragraph is extraneous information and should be placed elsewhere in the data element.	Moved down to notes
6.33 DateTime Specimen Collected –Usage	Conditions of Use refers to 'Incomplete dates' What about estimated dates? Misuse refers to entering approximate dates when an exact date is available. What is suggested for when an exact date isn't available?	An incomplete date is used for estimated dates – this is described in the datatype document. Using approximate (estimated) dates are suggested when an exact date isn't available. We now plan to describe this in the DateTime datatypes description on p.28 and all other datetime data elements in the document will point to this discussion.
6.34 Specimen Collection Setting	This data element is confusing, as the name refers to the setting but the definition includes information about who may be collecting the specimen. Suggest the definition state 'The place at which the specimen was collected from a client.' The 2nd sentence in the definition states that the specimen 'may be collected by the patient or patient's carer'. A specimen could be collected by anyone else, a friend etc and this is not a place. The 2nd sentence in the definition should be placed in the Notes section. The Notes section should be clarified as it refers to 'the specimen collection location within the healthcare setting', although the definition refers to a home setting.	Apparently there are now in draft some new rules about recording specimen collectors and specimen collection settings. We will be reviewing these elements in light of these new rules and will bear your suggestions in mind when conducting this redraft.
6.36 Specimen Characteristic	Perhaps this data element needs to be clear who assigns the characteristics.	Definition changed to read "The clinical finding of the reporting pathologist on initial"

6.38 Test Detail – Definition	<p>States “Details pertaining to an individual pathology test.” Should a different word to ‘individual’ be used here, as this could be confused with ‘an individual’ – subject of care/health care client?</p> <p>The 2nd paragraph of the definition should be placed in the Notes section.</p>	<p>Changed to “.. a singular.”</p> <p>Moved to notes</p>
6.39 Request Test Name	<p>The value domain indicates a different reference set to the value domain for the data element 6.42 Result Test Name. Is this the case? The Pathology Terminology Approach Document refers to a single list?</p>	<p>Approach Document.</p>
6.40 Result Detail – Definition	<p>Should the word ‘investigation’ rather than ‘test’ be used here as per the Request Test Name and Result Test Name data elements?</p>	<p>I don’t think this change adds meaning and I don’t think that there is any inherent contradiction in the particular usages.</p>
6.42 Result Test Name	<p>The value domain indicates a different reference set to the value domain for the data element 6.39 Request Test Name. Is this the case? The Pathology Terminology Approach Document refers to a single list?</p>	<p>See 6.39 above.</p>
6.43 Structured Result Entry – Definition	<p>Comment as above in regard to the possible use of the word ‘investigation’ rather than test.</p>	<p>See 6.40 above.</p>
6.44 Result Observable Name – Definition	<p>2nd paragraph is not part of the definition and should be moved to the Notes section.</p>	<p>Moved to notes</p>
6.47 Result Observable Reference Range – Definition	<p>2nd sentence is not part of the definition and should be moved to the Notes section.</p>	<p>Moved to notes</p>
6.50 Result Note	<p>2nd sentence is not part of the definition and should be moved to the Notes section.</p>	<p>Moved to notes</p>
6.51 Abnormal Result Indicator	<p>The definition describes more of a level rather than what an indicator is.</p> <p>The examples includes an Abnormal Result Indicator = Within normal limits for this condition, unsure how this aligns with this data element.</p> <p>How is an abnormal result defined?</p>	<p>I am unsure of the objection here and would be interested in discussing this further. The definition and examples given for this data element was reached with input from pathologists.</p>
6.52 Out Of Range Indicator	<p>Unsure how the examples tie in with this data element. It would seem that an out of range indicator should indicate ‘Yes’ and ‘No’. If ‘Y’ then an additional data element would identify what is the variance Low, High etc.</p>	<p>Once again, previous discussion around this data element decided that a “flag” is a yes/no – an “indicator” is used to describe levels. Could you please clarify your objection.</p>

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<p>6.53 Result Observable Status – Definition</p>	<p>Reporting Pathologist does not need to be in capitals.</p> <p>2nd paragraph should be removed from the definition and placed elsewhere.</p> <p>The name of this data element could be clearer to reflect the definition. The same applies to 6.59 Result Status data element.</p>	<p>It is in capitals because it is a hyperlink to a heading.</p> <p>Moved to notes</p> <p>What do you suggest would make it clearer</p>
<p>6.56 Report – Definition</p>	<p>The word 'actual' should be removed.</p>	<p>Change made.</p>
<p>6.59 Result Status</p>	<p>The name of this data element should be clarified and reflect the definition. This would also assist differentiating this data element from 6.53 Result Observable Status.</p>	<p>What do you suggest would make it clearer?</p>





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