Australian Government
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Pathology Report
Structured Content Specification

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Document information

Key information

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Product or document version history

Product or document version	Date	Release comments
1.0	31 Dec 2014	Initial release.
2.0	26 April 2022	Introduction of support for structured pathology results. Pathology Report v2.0 issues Pathology Report with Structured Clinical Content SCS Version 1.0 for use with one amendment to allow for multiple REPORTING PATHOLOGIST in the CONTEXT.
2.0	20 Feb 2025	The document presentation has been enhanced to align with current branding guidelines, however the content has not been changed.

Table of contents

1 Introduction

This document is a structured content specification (SCS) for pathology report documents. The scope includes test results and other structured clinical content.

We value your questions and comments about this document. Please direct your questions or feedback to help@digitalhealth.gov.au.

1.1 Document Purpose

This document describes the recommended structured content of pathology report documents for exchange between healthcare providers and the My Health Record system infrastructure in Australia.

The following specification is referred to in the text in such a way that some or all of its content constitutes requirements for the purposes of this specification:

- Pathology Report with Structured Clinical Content SCS v1.0 [DH2022d]

The content within this document provides reviewers (software development teams, architects, designers, clinicians, and informatics researchers) with the necessary information (or references to information held outside this document) to evaluate and assess the clinical suitability of the specification.

It is also a key input to the Pathology Report CDA Implementation Guide [DH2022b], which describes how to implement Agency-compliant service referral documents using the HL7 Clinical Document Architecture [HL7CDAR2].

1.2 Intended audience

This document is aimed at software development teams, architects, designers, clinicians, and informatics researchers who are responsible for the delivery of clinical applications, infrastructure components and messaging interfaces, and also for those who wish to evaluate the clinical suitability of the Agency-endorsed specifications.

1.3 Document scope

This document specifies the essential data groups, data elements, and the constraints that should be applied to them when creating a pathology report document for inclusion in the My Health Record system.

A pathology report is created by an authoring pathology provider in response to a pathology order and contains a pathologist's analysis of one or more test results. The original diagnostic report may be attached in one or more formats (e.g. PDF and MS

Word) that may contain one or more pathology test results. Thus, the values of pathology report elements present in structured data elements, and present in an attached report shall be consistent.

Support for general pathology (including biochemistry, haematology, and microbiology) is provided. Other areas, such as anatomical pathology and genetics, have not been fully considered in the design and further enhancement to the model will be required to meet the full spectrum of pathology results.

Full support for structured pathology reporting as defined in RCPA's structured pathology reporting of cancer [RCPA2021] is not yet supported. It is expected that this support is best handled by a set of designs that represent the structured reporting requirements for each specific protocol.

This specification is intended to be compatible with the previous version of this specification [NEHT2013u], (which does not have structured clinical content), and with the specification of structured pathology results in Event Summary Structured Content Specification [NEHT2015b]. It does not include any revision to the underlying concept of pathology test result.

This is not a guide to the implementation of any specific messaging standard.

This document is not to be used as a guide to presentation (or rendering) of the data. It contains no information as to how the data described by it should be displayed and no such guidance should be inferred from this document.

1.4 Known issues

This table lists known issues with this specification at the time of publishing. We are working on solutions to these issues and encourage comments to help us develop these solutions.

Reference	Description
Presentation and format	This specification issues an existing 2016 specification (Pathology Report with Structured Clinical Content SCS v1.0) for use in 2022. Due to tooling obsolescence that specification is issued as originally constructed in 2016 with amendments specified in this specification in chapter 2. Pathology Report Structured Document.
Pathology Test Result Detailed Clinical Model extant design issues	This specification is intentionally constrained to maximise compatibility with both Pathology Report Structured Content Specification v1.0 [NEHT2013u] and with the specification of pathology clinical content in Event Summary Structured Content Specification [NEHT2015b]. Therefore, known limitations with the underlying Pathology Test Result DCM (see Pathology Test Result

	Detailed Clinical Model Specification [NEHT2015j]) have not been addressed.
Alignment with the HL7™ Fast Healthcare Interoperability Resources (FHIR®) standard	The concept of a pathology report, as modelled in this specification, is not fully consistent with HL7 FHIR resources. This specification is intentionally constrained to the 2016 Pathology Test Result DCM and as such known limitations with the underlying model in alignment to FHIR have not been addressed.
Superseded standards	The model of a pathology report, as defined in this specification, makes use of superseded standards including terminology. This specification is intentionally constrained to the 2016 Pathology Test Result DCM and as such known limitations with the model in its use of superseded standards have not been addressed.

2 Pathology Report Structured Document

A Pathology Report Structured Document **SHALL** conform to the requirements specified in Pathology Report with Structured Clinical Content SCS v1.0 [DH2022d].

This specification, Pathology Report SCS v2.0, grants permission to use and disclose the content of Pathology Report with Structured Clinical Content SCS v1.0 [DH2022d] under the conditions and limitations in the front matter of this specification.

2.1 Amendment of Pathology Report with Structured Clinical Content SCS v1.0

The following amendments to the requirements of Pathology Report with Structured Clinical Content SCS v1.0 [DH2022d] apply.

2.4 PATHOLOGY REPORT, Data Hierarchy

Replace the cardinality of the REPORTING PATHOLOGIST in the CONTEXT with "1..*".

2.9 REPORTING PATHOLOGIST, Usage

Delete the following:

This document **SHALL** contain one instance of *REPORTING PATHOLOGIST* in the CONTEXT, or contain one instance of *REPORTING PATHOLOGIST* in each instance of *Pathology Test Result*, but not both.

2.9 REPORTING PATHOLOGIST, Relationships

In the Parents table, replace the value in the " Occurrences (child within parent)" column with "1..*".

3.90 REPORTING PATHOLOGIST, Usage

Delete the following:

This document **SHALL** contain one instance of *REPORTING PATHOLOGIST* in the CONTEXT, or contain one instance of *REPORTING PATHOLOGIST* in each instance of *Pathology Test Result*, but not both.

Appendix A Change history

This appendix provides a list of normative substantive changes since the previous version of this specification.

A.1 Changes from v1.0 published, 31 December 2014

Pathology Report v2.0 issues Pathology Report with Structured Clinical Content Structured Content Specification v1.0 [DH2022d] for use with amendment.

Changes comprise alterations and additions to Pathology Report v1.0 [NEHT2013u] by incorporating the requirements of Pathology Report with Structured Clinical Content Structured Content Specification v1.0 [DH2022d] with amendments applied.

A.1.1 Changes to CONTEXT

1 Changed REPORTING PATHOLOGIST from 1..1 to 1..*

2 Changed ORDER DETAILS > REQUESTER > Participation Period from 1..1 to 0..1

3 Added ORDER DETAILS > Requested Test Name (Order Name) 0..1

A.1.2 Changes to PATHOLOGY

1 Changed RELATED DOCUMENT from 1..1 to 0..1

A.1.3 Changes to PATHOLOGY TEST RESULT

1 Changed Test Specimen Detail (SPECIMEN) from 1..1 to 1..*

2 Added child data components to Test Specimen Detail (SPECIMEN) (see A.1.4)

3 Added Clinical Information Provided 0..1

4 Added Result Group (PATHOLOGY TEST RESULT GROUP) 0..* , and added child data components (see A.1.5)

5 Added Pathological Diagnosis 0..*

6 Added Conclusion 0..1

7 Added Test Result Representation 0..1

8 Added Test Comment 0..1

9 Added TEST REQUEST DETAILS 0..*, and added child data components (see A.1.8)

10 Added REPORTING PATHOLOGIST 0..1

A.1.4 Additions to Test Specimen Detail (SPECIMEN)

1 Specimen Tissue Type 0..1

2 Collection Procedure 0..1

3 Anatomical Site (ANATOMICAL LOCATION) 0..*, and added the following child data components:

   a SPECIFIC LOCATION 0..1, and added the following child data components:

      i Anatomical Location Name 0..1

      ii Side 0..1

   b Anatomical Location Description 0..1

   c Anatomical Location Image 0..*

4 Physical Details (PHYSICAL PROPERTIES OF AN OBJECT) 0..*, and added the following child data components:

   a Weight 0..1

   b DIMENSIONS 0..1, and added the following child data components:

      i Volume 0..1

   c Description (Object Description) 0..1

   d Image 0..1

5 COLLECTION AND HANDLING 0..1, and added the following child data components:

   a Sampling Preconditions 0..1

6 Added the following child data components to HANDLING AND PROCESSING:

   a Collection Setting 0..1

   b Date and Time of Receipt (`DateTime` Received) 0..1

7 IDENTIFIERS 0..1, and added the following child data components:

   a Specimen Identifier 0..1

   b Parent Specimen Identifier 0..1

   c Container Identifier 0..1

A.1.5 Additions in Result Group (PATHOLOGY TEST RESULT GROUP)

1 Pathology Test Result Group Name 1..1

2 Result (INDIVIDUAL PATHOLOGY TEST RESULT) 1..*, and added the following child data components:

   a Individual Pathology Test Result Name 1..1

b Result Value (INDIVIDUAL PATHOLOGY TEST RESULT VALUE) 0..1, and added child data components (see A.1.6)

c Individual Pathology Test Result Comment 0..*

d Individual Pathology Test Result Reference Range Guidance 0..1

e Individual Pathology Test Result Status 1..1

3 Added Result Group Specimen Detail (SPECIMEN) 0..1, and added child data components (see A.1.7)

A.1.6 Additions in Result Value (INDIVIDUAL PATHOLOGY TEST RESULT VALUE)

1 Individual Pathology Test Result Value 1..1

2 Individual Pathology Test Result Value Reference Ranges (REFERENCE RANGE DETAILS) 0..1, and added the following child data components:

a Normal Status 0..1

b REFERENCE RANGE 0..* , and added the following child data components:

i Reference Range Meaning 1..1

ii Reference Range 1..1

A.1.7 Additions in Result Group Specimen Detail (SPECIMEN)

1 Specimen Tissue Type 0..1

2 Collection Procedure 0..1

3 Anatomical Site (ANATOMICAL LOCATION) 0..*, and added the following child data components:

a SPECIFIC LOCATION 0..1, and added the following child data components:

i Anatomical Location Name 0..1

ii Side 0..1

b Anatomical Location Description 0..1

c Anatomical Location Image 0..*

4 Physical Details (PHYSICAL PROPERTIES OF AN OBJECT) 0..*, and added the following child data components:

a Weight 0..1

b DIMENSIONS 0..1, and added the following child data components:

i Volume 0..1

c Description (Object Description) 0..1

d Image 0..1

5 COLLECTION AND HANDLING 0..1, and added the following child data components:

a Sampling Preconditions 0..1

6 HANDLING AND PROCESSING 1..1, and added the following child data components:

a Date and Time of Collection (Collection `DateTime`) 1..1

b Collection Setting 0..1

c Date and Time of Receipt (`DateTime` Received) 0..1

7 IDENTIFIERS 0..1, and added the following child data components of IDENTIFIERS:

a Specimen Identifier 0..1

b Parent Specimen Identifier 0..1

c Container Identifier 0..1

A.1.8 Additions in TEST REQUEST DETAILS

1 Requester Order Identifier 0..1

2 Test Requested Name 0..1

3 Laboratory Test Result Identifier 0..1

Acronyms

Acronym	Description
CDA	Clinical Document Architecture
DCM	Detailed Clinical Model
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level Seven
NCTIS	National Clinical Terminology and Information Service
OID	Object Identifier
PR	Pathology Report
RCPA	Royal College of Pathologists of Australasia
SCS	Structured Content Specification

References

[DH2022b] Australian Digital Health Agency, 26 April 2022, Pathology Report CDA Implementation Guide v2.0. https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-3533-2022

[DH2022d] Australian Digital Health Agency, 26 April 2022, Pathology Report with Structured Clinical Content Structured Content Specification v1.0. https://developer.digitalhealth.gov.au/specifications/clinical- documents/ep-3533-2022

[HL7CDAR2] Health Level Seven, Inc., January 2010, HL7 Clinical Document Architecture, Release 2. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

[NEHT2013u] National E-Health Transition Authority, 31 December 2014, Pathology Report Structured Content Specification, v1.0. https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-2558-2017

[NEHT2015b] National E-Health Transition Authority, 10 April 2015, Event Summary Structured Content Specification, v1.2. https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep- 1817-2015

[NEHT2015j] National E-Health Transition Authority, 18 December 2015, Pathology Test Result Detailed Clinical Model Specification, v3.1. https://developer.digitalhealth.gov.au/specifications/clinical- documents/ep-2522-2017

[RCPA2021] Royal College of Pathologists of Australasia, 06 August 2021, Structured Pathology Reporting of Cancer, accessed 13 September 2021. https://www.rcpa.edu.au/Library/Practising-Pathology/Structured-Pathology-Reporting-of-Cancer