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eHealth Pathology Report
PCEHR Conformance Profile v1.0.1

31 July 2015

Approved for external use

Document ID: NEHTA-1979:2015

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Acknowledgements

Council of Australian Governments
The National E-Health Transition Authority is jointly funded by the Australian Government and all State and Territory Governments.

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Document information

Key information

Owner	Head of Delivery
Document generation details	Word Publisher version : 2.138 Generated date : 14/01/2015 3:25 PM
Contact for enquiries	NEHTA Help Centre t: 1300 901 001 e: help@nehta.gov.au

Product version history

Product version	Date	Release comments
1.0	23 February 2015	Initial release to early implementers
1.0.1	31 July 2015	First public release

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1 Introduction

1.1 Purpose

This document summarises the requirements for producers and consumers of eHealth Pathology Reports that connect to the personally controlled electronic health record (PCEHR) system.

This document lists the specific conformance requirements for eHealth Pathology Reports that are in addition to the *Common Conformance Profile for Clinical Documents* [NEHTA2015a] and the generic requirements listed in the *Clinical Information Systems Connecting to the PCEHR System* [NEHTA2012a]. Together, these documents represent the complete conformance requirements for eHealth Pathology Reports.

1.2 Intended audience

The intended audience includes:

- Healthcare providers;
- Vendors and developers of software systems; and
- Software test laboratories.

1.3 Scope

1.3.1 In scope

An eHealth Pathology Report is created by an authoring pathology provider and contains the pathologist's analysis of one or more test results.

An eHealth Pathology Report is a Clinical Document Architecture (CDA®) document that contains a single PDF attachment that may itself contain one or more pathology test results.

The following roles may be performed by software systems:

- *eHealth Pathology Report producer* - A software system used by a pathology provider to create an eHealth Pathology Report.
- *eHealth Pathology Report consumer* - A software system that has the role of being a consumer of eHealth Pathology Reports.

1.3.2 Out of scope

There are specific requirements related to the management of pathology results provided to the PCEHR, which are managed by the PCEHR system itself. One of those requirements is for reports to be immediately available to authorised healthcare providers however reports are to be withheld from the consumer portal for a defined period (currently seven days). This requirement is out of scope for eHealth Pathology Report producer and consumer conformance.

2 Relevant specifications

The detailed conformance requirements are listed below:

1. *Common Conformance Profile for Clinical Documents* [NEHTA2015a] provides common conformance requirements that must be adhered to, unless specifically contradicted in this document.
2. *eHealth Pathology Report Structured Content Specification* [NEHTA2014c] specifies the data elements and constrained values for an eHealth Pathology Report at a logical level.
3. *eHealth Pathology Report CDA Implementation Guide* [NEHTA2014d] specifies the mapping from the structured content specification into a CDA® document using an HL7® CDA® structure.

3 Requirements for producers

023456 **Disallowed types of producers**

A producer **SHALL NOT** be a:

- registered consumer portal; or
- registered provider portal.

Priority Mandatory

023435 **Document conformance levels**

A CDA® document sent to the PCEHR system **SHALL** conform to the requirements for one, and only one, of the following conformance levels: 3A or 3B as defined in the *Common Conformance Profile for Clinical Documents* [NEHTA2015a].

Priority Mandatory

3.1 Requirements for pathology test results

023473 **CDA® document has a PDF packaged attachment**

A CDA® document **SHALL** reference one, and only one, attachment that is the original diagnostic report. The report **SHALL** be a PDF packaged attachment.

Priority Mandatory

Additional notes The requirement applies only to attachments that include diagnostic test results. Other types of attachments (e.g. a logo) may be included. The original diagnostic report should only be made available in the PCEHR system in PDF format to ensure that the presentation and rendering of the data is as expected by the authoring healthcare provider. The PDF file may contain details of one or more diagnostic examinations or procedures.

The PDF file is expected to be viewable by the healthcare individual and any healthcare provider that is a PCEHR participant. For example, the diagnostic report PDF files should not be have any of these features:

- Encryption
- Password protection
- Printing / copying restriction
- Embedded fonts (as not all PDF viewers support them)
- Do not restrict changes (changes are not allowed regardless of whether this PDF flag is set)

023651 **Consistency between information in the CDA® document and PDF document**

The values of diagnostic report data elements that are present in both the CDA® document and the PDF document **SHALL** be consistent.

Priority Mandatory

Additional notes This is to reduce the risk that CDA® data items conflict with data within the diagnostic report PDF document.

024692 **Some eHealth Pathology Report information must be present to support the PCEHR view**

The value of the following data elements **SHALL NOT** be a nullFlavor:

- Document Author > Participant > Person or Organisation or Device > Person > Employment Detail > Employer Organisation > Organisation > Organisation Name
- Order Details > Requester > Participant > Person or Organisation of Device > Person > Person Name > Family Name
- Pathology > Pathology Test Result > Test Result Name
- Pathology > Pathology Test Result > Test Specimen Detail > Handling and Processing > Collection DateTime
- Pathology > Pathology Test Result > Pathology Discipline
- Pathology > Pathology Test Result > Overall Test Result Status
- Pathology > Related Document > Document Details > Report Identifier
- Pathology > Related Document > Document Details > Report DateTime

Priority Mandatory

Additional notes These data elements are presented in the eHealth Pathology Report View created by the PCEHR system, so they must have an actual value rather than a nullFlavor.

Overall Test Result Status is an optional data element but, if included, needs to have an actual value not a nullFlavor.

In DateTime data elements, including the time is optional and is only to be provided if the time is known.

024798 **Order test results in CDA® document and PDF attachment consistently**

The diagnostic report provider software **SHOULD** sort the test result details in the CDA® document in the same order as displayed in the report PDF document.

Priority Recommended

Additional notes Inconsistent ordering of results within a report may confuse the user, reduce the user experience, cause results and result updates to be missed and, in extreme cases, may impact clinical decision making.

026615 **Omission of the Pathology Test Result section title**

If a narrative is not included in a Pathology Test Result section then the section title **SHALL NOT** be included.

Priority Conditional

Additional notes The purpose of this requirement is to state that when there is no narrative block, then the title for the narrative block must not be present.

Each pathology test result is recorded in a section within the Pathology Report section of the CDA® document. The *Pathology Report CDA Implementation Guide* [NEHTA2014d] specifies the inclusion of a narrative block for each pathology test result section but that may be omitted using requirement 025052 in the *Common Conformance Profile for Clinical Documents* [NEHTA2015a].

3.2 Document author and reporting pathologist

The document author is responsible for composing the pathology report, whereas a reporting pathologist is responsible for one or more pathology test results. Therefore it is possible that the reporting pathologist may also be the document author. When there is more than one reporting pathologist, it is possible that one of them may also be named as the document author.

The information model described in the *eHealth Pathology Report Structured Content Specification* [NEHTA2014c] has the following constraints:

1 It does not allow multiple reporting pathologists to be recorded in the CDA® document, though they may be recorded in the attached PDF file.

2 It requires the composer of the document (i.e. the document author) to be one person and one person only.

Requirements are defined here to resolve these constraints. When the constraints are removed in the information model, then the requirements stated here will be revised.

In addition, the PCEHR System Operator is relaxing the mandatory requirement for inclusion of an HPI-I, with the relaxation being available to specific healthcare provider organisations.

023436	**Identifier for Document Author** The value of one Document Author > Participant > Entity Identifier **SHALL** be an HPI-I if one is present or can be obtained from the Healthcare Identifiers Service, otherwise it **SHALL** have a value that identifies the document author and the value **SHALL NOT** be a nullFlavor.
Priority	Mandatory
Additional notes	The PCEHR structured content specifications and CDA® implementation guides include a requirement mandating the inclusion of an HPI-I for the Document Author. The above requirement overrides that requirement. The relaxation of the mandatory requirement to include an HPI-I is only available to specific healthcare provider organisations, at the discretion of the PCEHR System Operator. The *Common Conformance Profile for Clinical Documents* [NEHTA2015a] provides requirements for the local identifiers of the type that are managed by a healthcare provider. Examples of other types of local identifiers are provided by the *Healthcare Identifier HL7 Implementation Guide* [SA2012].

025065 **When the Document Author is not one person**

The following values **SHALL** be used for mandatory Document Author data elements when it is not possible to name one person as the Document Author:

- Document Author > Role **SHALL** have the value nullFlavor="NI"
- Document Author > Participant > Entity Identifier **SHALL** be a local identifier with the value "NI" for the extension attribute
- Document Author > Participant > Person or Organisation or Device > Person > Person Name > Family Name **SHALL** have the value nullFlavor="NI".

Priority Mandatory

Additional notes The structured content specification and CDA® implementation guide mandate that one person be named as the Document Author. This modification of the specifications will not be needed when the specifications are revised to cater for the scenario where there is no single person in the role of Document Author.

The *Common Conformance Profile for Clinical Documents* [NEHTA2015a] provides requirements for the inclusion of local identifiers.

The nullFlavor "NI" is an abbreviation for "no information" and means that no information whatsoever can be inferred.

Note that even though a person is not being named and identified as the Document Author, the mandatory inclusion of Employment Detail still applies. The information to include in the Employment Detail includes the name and identifier of the organisation that created the CDA® document. See the CDA® implementation guide for a description of information that must be included in the author's Employment Detail. The mandatory inclusion of the Participation Period still applies.

023648	**Identifier for reporting pathologist** The value of one Reporting Pathologist > Participant > Entity Identifier **SHALL** be an HPI-I if one is present or can be obtained from the Healthcare Identifiers Service, otherwise it **SHALL** have a value that identifies the reporting pathologist and the value **SHALL NOT** be a nullFlavor.
Priority	Mandatory
Additional notes	The eHealth Pathology Report structured content specification and CDA® implementation guide include a requirement mandating the inclusion of an HPI-I for the reporting pathologist. The above requirement overrides that requirement. The relaxation to the mandatory requirement to include an HPI-I is only available to specific healthcare provider organisations, at the discretion of the PCEHR System Operator. The *Common Conformance Profile for Clinical Documents* [NEHTA2015a] provides requirements for the local identifiers of the type that are managed by a healthcare provider. Examples of other types of local identifiers are provided by the *Healthcare Identifier HL7 Implementation Guide* [SA2012].

025066 **Multiple reporting pathologists**

The following values **SHALL** be used for mandatory Reporting Pathologist data elements when it is not possible to name one person as the Reporting Pathologist:

- Reporting Pathologist > Role **SHALL** have the value nullFlavor="NI".
- Reporting Pathologist > Participant > Entity Identifier **SHALL** be a local identifier with the value "NI" for the extension attribute.
- Reporting Pathologist > Participant > Person or Organisation or Device > Person > Person Name > Family Name **SHALL** have the value nullFlavor="NI".

Priority Mandatory

Additional notes This usage of the reporting pathologist data element is permitted until the specifications are revised to enable more than one reporting pathologist to be recorded.

Note that Reporting Pathologist > Participant > Address and Reporting Pathologist > Participant > Electronic Communication Detail are mandatory and used to provide contact details for the reporting pathologist(s).

The *Common Conformance Profile for Clinical Documents* [NEHTA2015a] provides requirements for the inclusion of local identifiers.

The nullFlavor "NI" is an abbreviation for "no information" and means that no information whatsoever can be inferred.

Note that even though one person is not being named and identified as the reporting pathologist, the mandatory inclusion of Employment Detail still applies. The information in the Employment Detail includes the name and identifier of the organisation that employed the reporting pathologist(s). See the *eHealth Pathology Report CDA Implementation Guide* [NEHTA2014d] for a description of information that must be included in the Employment Detail. The mandatory inclusion of the Address and Participation Period still applies.

When there are multiple reporting pathologists, they may all be listed in the pathology report PDF file and either none or one can be listed in the CDA® document.

3.3 Healthcare identifier validation requirements

The PCEHR system relies on healthcare software to ensure that an IHI is correct for a healthcare individual. Therefore the default requirements applying to healthcare software accessing the PCEHR system [NEHTA2012b] mandate that the software has access to the Healthcare Identifiers Service and that the software uses an IHI only if it has been obtained or validated within a configurable period (see requirement 019100[1] in the *Clinical Information Systems Connecting to the PCEHR System Conformance Requirements* [NEHTA2012b]).

The default requirements are modified here so that software used by a diagnostic services provider need not have access to the Healthcare Identifiers Service if the software only ever receives electronic requests for diagnostic services. The default requirements still apply for software that may receive paper requests for diagnostic services.

024885	**Healthcare identifier received via electronic request does not require revalidation** If the software has no access to the HI Service, the software **MAY** use a healthcare identifier received via an electronic request without needing to revalidate the healthcare identifier.
Priority	Optional
Additional notes	This has the effect that conformance to requirement 019100 in the *Clinical Information Systems Connecting to the PCEHR System Conformance Requirements* [NEHTA2012b] is now optional for software that produces diagnostic reports when a healthcare identifier is contained within an electronic request.

[1] The wording of requirement 019100 states that the software must be connected to the HI Service or else obtain an IHI from another software application connected to the HI Service. That allows an IT environment to have multiple applications where one accesses the PCEHR system and another application accesses the HI Service. However, the IT environment operates within the boundary of a healthcare provider organisation.

024972	**Access to the Healthcare Identifiers Service** The software **MAY** have no access to the Healthcare Identifiers Service if the software only uses healthcare identifiers received via electronic requests.
Priority	Optional
Additional notes	A standard mandatory requirement for software that accesses the PCEHR system is for the software to use the Healthcare Identifiers Service to ensure the validity of an IHI (see requirement 019100 in *Clinical Information Systems Connecting to the PCEHR System, Conformance Requirements* [NEHTA2012b]). The effect of the above requirement is to make requirement 019100 optional if the software only ever uses IHIs received via electronic requests. Software uploading a diagnostic report following the receipt of a paper request must use the Healthcare Identifiers Service for validation, as stated in requirement 019100.

3.4 Consent management requirements

When registering for a PCEHR, the consumer agrees to provide 'standing consent' to information being uploaded to their PCEHR by any healthcare provider participating in the PCEHR program. However the consumer may actively dissent to specific documents being uploaded to the PCEHR system.

The conformance requirements allow for the requester to provide consumer consent status information to diagnostic reports being uploaded to their PCEHR. A request for diagnostic services may result in one or more diagnostic reports being generated by a diagnostic service provider. Therefore consent settings are linked to the request for diagnostic services rather than an individual diagnostic report.

The following consent settings are to be recorded in the diagnostic service provider's software so that the consent of the healthcare individual is considered when creating diagnostic reports.

- **'Consent Indicated'** means the healthcare individual has provided their consent. This may be because either the healthcare individual has explicitly stated their consent (e.g. to the requester) or the software operated by the requester or diagnostic service provider has determined the healthcare individual has standing consent.
- **'Consent Withdrawn'** means the healthcare individual has stated they do not want one or more diagnostic reports to be uploaded to their PCEHR, despite the existence of their standing consent.
- **'Consent Not Indicated'** means it has not been possible for the diagnostic service provider software to determine the consent status of the healthcare individual.

It is not expected that software will store these names and instead may store a code corresponding to one of these settings.

Once the consent setting has been recorded, the setting 'Consent Withdrawn' may be subsequently updated to 'Consent Indicated'. However the 'Consent Indicated' setting may only be changed to 'Consent Withdrawn' where a report(s) associated with the request has not already been uploaded to the PCEHR. Where a report has already been uploaded, the healthcare individual can remove or restrict access to the report using the PCEHR consumer portal or by contacting PCEHR operational support.

The diagnostic service provider may choose to prevent a report being uploaded to the PCEHR system even when 'Consent Indicated' has been recorded, e.g. due to a concern or issue about the content of the report.

Information about consent may be conveyed by a requester to a diagnostic service provider in various ways, including in a paper or electronic request, or after the request is issued (e.g. over the telephone or electronic communication). The requirements make no assumptions about the format or content of this communication.

025081 **Indication of consent in a request**

When a paper or electronic request indicates the healthcare individual has provided their consent, then the setting 'Consent Indicated' **SHALL** be recorded. All diagnostic reports produced as a result of the request **SHALL** be uploaded to the PCEHR system, unless a healthcare provider in the diagnostic organisation decides the report is not to be uploaded or if there is a technical reason preventing a report from being uploaded.

Priority Mandatory

Additional notes It is not expected that software will store the text 'Consent Indicated' and instead may store a corresponding code.

025082 **Indication of withdrawal of consent in a request**

When a paper or electronic request indicates the healthcare individual has withdrawn their consent, then the setting 'Consent Withdrawn' **SHALL** be recorded. Diagnostic reports produced as a result of the request **SHALL NOT** be uploaded to the PCEHR system while the consent setting is 'Consent Withdrawn'.

Priority Mandatory

Additional notes It is not expected that software will store the text 'Consent Withdrawn' and instead may store a corresponding code.

025070 **Standing consent applies when a request does not explicitly contain consent settings**

The software **SHALL** apply a healthcare individual's standing consent when a request is received that does not explicitly contain consent settings.

1. If the PCEHR is found to exist, then the software **SHALL** record 'Consent Indicated'.
2. If the PCEHR is not found, then the software **SHALL** record 'Consent Not Indicated'.
3. If the attempt to find the PCEHR returns an error, then the software **SHALL** record 'Consent Not Indicated'.

Priority Mandatory

Additional notes If the request neither indicates the healthcare individual's consent nor indicates their withdrawal of consent, then the software needs to determine if the healthcare individual has standing consent. Standing consent is determined by calling doesPCEHRExist to determine if there is an advertised PCEHR for the healthcare individual.

025079 **Allow a change from 'Consent Withdrawn' to 'Consent Indicated'**

The software **SHALL** allow a consent setting to be changed from 'Consent Withdrawn' to 'Consent Indicated'. The software **SHALL** upload to the PCEHR system the latest version of any diagnostic reports that were not uploaded while the consent setting was 'Consent Withdrawn', with the exception of any diagnostic reports that the diagnostic service provider has decided to not upload.

Priority Mandatory

Additional notes This requirement applies only to diagnostic reports created in response to the current request for diagnostic services. It does not apply to diagnostic reports created in response to historical requests for diagnostic services.

The requirement allows a healthcare provider to notify the diagnostic service provider of a change of consent. A diagnostic service provider is expected to be able to support a change of consent that is communicated from a healthcare provider.

The change of consent may also be communicated by the healthcare individual directly to the diagnostic service provider.

025154 **Allow a change from 'Consent Indicated' to 'Consent Withdrawn'**

The software **SHALL** allow a consent setting to be changed from 'Consent Indicated' to 'Consent Withdrawn' when reports generated for the request have not already been uploaded to the PCEHR. Diagnostic reports produced as a result of the request **SHALL NOT** be uploaded to the PCEHR system while the consent setting is 'Consent Withdrawn'.

The software **SHALL NOT** allow a consent setting to be changed from 'Consent Indicated' to 'Consent Withdrawn' when reports generated for the request have already been uploaded to the PCEHR.

Priority Mandatory

Additional notes This requirement allows the healthcare individual to advise the change of consent directly to the diagnostic service provider.

Where a report has already been uploaded, the healthcare individual can remove or restrict access to the report using the PCEHR consumer portal or by contacting PCEHR operational support.

025080 **Support a diagnostic service provider's right to upload or not upload a diagnostic report**

When a diagnostic service provider has decided to not upload a diagnostic report despite a healthcare individual's consent, the software **SHALL** allow the diagnostic report to be uploaded at a later time.

Priority Mandatory

Additional notes A standard mandatory requirement for software that accesses the PCEHR system is for the software to not upload a CDA® document to the PCEHR system, if requested by a healthcare provider (see requirement 017839 in *Clinical Information Systems Connecting to the PCEHR System Conformance Requirements* [NEHTA2012b]).

A diagnostic service provider may decide to not upload the diagnostic report due to a concern or issue about the content of the report. Once the concern or issue is resolved, the report may be uploaded to the PCEHR system.

3.5 Record keeping requirements

26625 **Record a failure to upload a diagnostic report**

The software **SHALL** record a failure to upload a diagnostic report to the PCEHR system. The information recorded **SHALL** include the report identifier, the error code returned by the PCEHR system and the date and time. The information recorded **SHOULD** include the requester's order identifier.

Priority Mandatory

Additional notes Keeping a record of upload failures will enable the requester to determine why a report could not be uploaded to the PCEHR system, and is needed given that the organisation responsible for uploading the diagnostic report is not the healthcare provider organisation with contact with the healthcare individual.

There is also a requirement to keep a record of diagnostic reports successfully uploaded to the PCEHR system (see requirement 017842 in *Clinical Information Systems Connecting to the PCEHR System Conformance Requirements* [NEHTA2012b]).

26626 **Record a failure to create a diagnostic report due to healthcare identifier validation failure**

If the software uses the Healthcare Identifiers Service to obtain or ensure the validity of an IHI or other healthcare identifier, the software **SHALL** record a failure to create a diagnostic report when the reason for the failure is an inability to obtain or validate one or more healthcare identifiers. The information recorded **SHALL** include the report identifier, the reason for the validation failure and the date and time. The information recorded **SHOULD** include the requester's order identifier.

Priority Conditional

Additional notes The reason for failure can be a fixed value. That is, there is no requirement for a user to be able to manually enter the reason.

The requirement applies only when there is an intention to create a diagnostic report, i.e. when the healthcare individual has consented to the report being uploaded to the PCEHR system.

26627 **Record a decision to not upload a diagnostic report by a diagnostic service provider**

The software **SHALL** record a decision by a diagnostic service provider to not upload a diagnostic report despite a consent setting of 'Consent Indicated'. The information recorded **SHALL** include the report identifier the date and time of the decision. The information recorded **SHOULD** include the requester's order identifier.

Priority Mandatory

Additional notes A healthcare provider in an organisation that creates diagnostic report may decide to not upload a diagnostic report to the PCEHR system even though the healthcare individual had consented to its upload (see requirement 017839 in *Clinical Information Systems Connecting to the PCEHR System Conformance Requirements* [NEHTA2012b]).

Keeping a record of a decision to not upload the report will enable the requester to determine why a report was not uploaded to the PCEHR system.

The method of recording and the format of the information is not specified by this requirement. In addition, there is no requirement for a user to be able to manually enter a reason for the decision.

26628 **Record the reversal of a diagnostic service provider's decision to not upload a diagnostic report**

The software **SHALL** record the reversal of a decision by a diagnostic service provider to not upload a diagnostic report despite a consent setting of 'Consent Indicated'. The information recorded **SHALL** include the report identifier, the date and time of the reversal of the decision. The information recorded **SHOULD** include the requester's order identifier.

Priority Mandatory

Additional notes Keeping a record of a decision to not upload the report will enable the requester to determine why a report was not uploaded to the PCEHR system.

The record of the decision can be a fixed value. That is, there is no requirement for a user to be able to manually enter a reason for the decision.

26629	**Record the original and changed consent settings**
	The software **SHALL** record the original consent setting associated with a request for diagnostic services. The software **SHALL** also record any change to the consent setting. The information recorded **SHALL** include the consent setting, the report identifier and the date and time. The information recorded **SHOULD** include the requester's order identifier.
Priority	Mandatory
Additional notes	The consent settings are 'Consent Indicated', 'Consent Withdrawn' and 'Consent Not Indicated'. It is not expected that software will store these names and instead may store a code corresponding to one of these settings.

025083	**Retrievable records**
	The software **SHALL** have the capability to retrieve and display the records of a failure to create or upload a diagnostic report; a decision, and reversal of a decision, to not upload a diagnostic report; and the original and changed consent settings.
Priority	Mandatory
Additional notes	Audit information will need to be made available to the PCEHR System Operator upon request.

3.6 Packaging requirements

Requirements listed here extend the set of packaging requirements listed in the *CDA Package* specification [NEHTA2011a] and *CDA Rendering Specification* [NEHTA2012c].

024732 **External references are allowed**

A diagnostic report, including the attached PDF file, **MAY** reference an object outside of the CDA® package (e.g. an external atomic attachment or a website).

Priority Optional

Additional notes This requirement has the effect of overriding *CDA Rendering Specification* [NEHTA2012c] requirements CDA-RS 53(g) and CDA-R5 53(j), which apply to CDA® document authoring systems and disallow references to items on a network. This override is needed as a diagnostic report may include a reference to supporting information on a website.

As a diagnostic report uploaded to the PCEHR system will be available to the healthcare individual and all participant healthcare providers for an indefinite period of time, software developers should avoid using references that may become broken after the CDA® document is created.

A reference to an object outside of the CDA® package may be included in the diagnostic report PDF file, or the CDA® document, or both. Objects outside of the CDA® package are regarded as 'external objects' and may be referenced according to the requirements stated in the HL7® *Clinical Document Architecture, Release 2* specification [HL72005] for external objects. For example, that specification mandates the use of <linkHtml> rather than <renderMultiMedia> to reference an external object from a narrative block.

4 Requirements for consumers

Requirements are listed here for the display and printing of a pathology report. These are additional to the existing requirements stated in the *Common Conformance Profile for Clinical Documents* [NEHTA2015a] and *Clinical Information Systems Connecting to the PCEHR System Conformance Requirements* [NEHTA2012a].

The use of a pathology report view to select a pathology report for display is recommended (see the *eHealth Pathology Report View - PCEHR Conformance Profile* [NEHTA2014f]).

024858 **Display the requester's order identifier (if available)**

The software **SHALL** display the requester's order identifier (if available) when the CDA® document is rendered.

Priority Mandatory

Additional notes If the requester's order identifier is known, it is recorded in the extension attribute of the inFulfillmentOf/Order/id data element.

The effect of this requirement is to add the requester’s order identifier (with XPath inFulfillmentOf/Order/id) to the table of CDA® document header details that must be rendered (see Table 2 in the *CDA Rendering Specification* [NEHTA2012c]).

024874 **Display the request date and time (if available)**

The software **SHALL** display the request date and time (if available) when the CDA® document is rendered.

Priority Mandatory

Additional notes The date and time (if available) of the request is recorded in the ClinicalDocument/participant/time data element.

The effect of this requirement is to add the request date and time (with XPath ClinicalDocument/participant/time) to the table of CDA® document header details that must be rendered (see Table 2 in the *CDA Rendering Specification* [NEHTA2012c]).

024886 **Display the diagnostic report PDF document in-line**

The software **SHOULD** display the diagnostic report PDF attachment in-line with the CDA® document.

Priority Recommended

Additional notes In-line rendering is a means of rendering on a screen an attachment (PDF document) with all or part of the CDA® document on the same window/view in such a way that it appears as a single document.

This requirement has the effect of overriding *CDA Rendering Specification* [NEHTA2012c] requirement CDA-RS 60, which applies to CDA® document rendering systems and disallows in-line rendering of attachments.

Depending on how a rendering system implements in-line rendering, other risks may need to be considered, including:

1. How the PDF document is presented to viewers.

2. How the PDF document prints within the rendered CDA® document.

3. How the in-line rendering is displayed on various browsers (if viewed from a web portal).

4. How the in-line rendering is displayed on various devices that may have access, including mobile devices.

5. Security considerations that an organisation may need to assess if a PDF is rendered in-line.

These considerations may result in an inability to implement in-line rendering.

025084 **Printing the PDF document**

If the software supports printing and performs in-line rendering of PDF documents, then the software **SHALL** print both the CDA® document and the attached diagnostic report PDF file when the user requests the CDA® document to be printed.

Priority Conditional

Glossary

Term	Meaning
AMT	Australian Medicines Terminology
approver	A person responsible for approving the contents of a clinical document [NEHTA2011a]. The approver cannot be a device or organisation.
atomic attachment	An atomic attachment is a single byte stream. For example, a JPEG image (c.f. the definition of an atomic packaged attachment defined in the *CDA package* specification [NEHTA2011a]).
Clinical Document Architecture (CDA®)	An XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents exchanged between health software systems. Specifications for clinical documents are based on *Clinical Document Architecture, Release 2* [HL72005].
CDA® IG	Clinical Document Architecture implementation guide
CIS	clinical information system
clinical document	A digital file containing personal health information about an individual, containing unstructured (narrative) information and optionally structured (atomic) information.
clinical information system (CIS)	A system that deals with the collection, storage, retrieval, communication, and use of health related data, information and knowledge pertaining to subjects of care [SA5021]. The system may comprise one or more applications or components.
conformance	A measurement (by testing) of the adherence of an implementation to a specification or standard.
consumer	In this document 'consumer' refers to a software system that has the role of being a consumer of clinical documents.
contracted service provider (CSP)	An entity that may offer health software as a service, and support access to the PCEHR system on behalf of healthcare organisations. A CSP provides under a contract with the healthcare provider organisation: a) information technology services relating to the PCEHR system; or b) health information management services relating to the PCEHR system. (Section 5 *PCEHR Act 2012* [COM2012].)
CSP	contracted service provider
CSP system	A software system operated by a CSP that deals with information pertaining to subjects of care [SA5021]. May comprise one or more applications or components. May perform some or all of the functions of a CIS.
CSP registration number	A number that uniquely identifies a CSP. The number has 16 digits, commences with '800363', and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
custodian	The custodian of a clinical document is the organisation that is responsible for maintaining the information in the clinical document. The information maintained by the custodian may be in a propriety format, rather than CDA® [HL72005].
diagnostic report	A generic term used to describe an eHealth Diagnostic Imaging Report or an eHealth Pathology Report. In a healthcare environment, other types of documents may be regarded as diagnostic report but uses other than eHealth Diagnostic Imaging Report or eHealth Pathology Report are out of scope in the context of this conformance profile.

Term	Meaning
digital signature	Signs the clinical document inside a signed CDA® package. The digital signature is contained within the eSignature.
eSignature	An eSignature is included in a signed CDA® package to attest to the contents of the clinical document (and indirectly its packaged attachments) [NEHTA2011a]. An eSignature contains a digital signature, identifies the approver and signing time, so in addition to the attestation it is also a mechanism to prevent forgery and to detect tampering of that assertion, and/or of the data being asserted.
external atomic attachment	An atomic attachment that is external to the CDA® package.
healthcare individual	A person who is the subject of care.
healthcare provider organisation	An enterprise that provides healthcare (including healthcare provided free of charge) [COM2012].
HI	Healthcare identifier: an identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient.
HL7®	HL7 is a trademark of Health Level Seven International.
HPI-I	A national identifier that uniquely identifies a healthcare provider individual. The identifier has 16 digits, commences with '800361' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
HPI-O	A national identifier that uniquely identifies a healthcare provider organisation. The identifier has 16 digits, commences with '800362' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
IHI	A national identifier that uniquely identifies a healthcare recipient. The identifier has 16 digits, commences with '800360' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
legal authenticator	An approver who legally authenticates the accuracy of an act. For example, a staff physician who sees a patient and dictates a note, then signs it [HL72005]. A legal authenticator provides a signature.
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
NASH	National Authentication Service for Health
OID	object identifier
object identifier	An ordered list of primary integer values from the root of the international object identifier tree to a node, which unambiguously identifies that node.
packaged attachment	A packaged attachment is defined as an attachment that is external to the CDA® XML document, included in the same CDA® package as the CDA® XML document; and it is referenced appropriately (*CDA Package* specification [NEHTA2011a]).
Participation Period	The time interval during which the participation in the health care event occurred.
P2P	Provider-to-provider: documents sent from one healthcare provider to another.
PCEHR	personally controlled electronic health record

Term	Meaning
PCEHR system	National eHealth infrastructure for managing records in eHealth records. The PCEHR system includes the PCEHR repository and the National Prescription And Dispense Repository.
PKI	Public-key infrastructure: a set of hardware, software, people, policies, and procedures to create, manage, distribute, use, store, and revoke digital certificates.
PKI certificate	A string that mathematically combines a PKI private key with the content of a message to cryptographically bind the message content to the PKI certificate associated with the private key. The PKI certificates used with clinical documents are NASH PKI certificates [DHS2013].
producer	In this document 'producer' refers to a software system that has the role of generating and issuing conformant clinical documents suitable for use by other participants in the eHealth.
registered consumer portal	A third-party portal used by healthcare recipients to access information on the PCEHR system.
registered portal operator	A person who is the operator of an electronic interface that facilitates access to the PCEHR system; and who is registered as a portal operator under section 49 of the *PCEHR Act 2012* [COM2012].
registered provider portal	A third-party portal used by healthcare providers to access information on the PCEHR system.
registered repository	A third-party repository used to store clinical documents and other clinical data that connects to the PCEHR system. May store clinical documents in either a proprietary format or a CDA® format.
registered repository operator	A person who holds, or can hold, records of information included in personally controlled electronic health records for the purposes of the PCEHR system, and who is registered as a repository operator under section 49 of the PCEHR Act 2012 [COM2012].
request	A request to create a diagnostic report, initiated and generated by a healthcare provider such as a GP or a specialist.
requester	The healthcare provider individual that issued a request.
SCS	Structured content specification
SHALL	When appearing in a conformance requirement, this verb **SHALL** indicates a mandatory requirement. Its negative form **SHALL NOT** indicates a prohibition.
SHOULD	When appearing in a conformance requirement, the verb **SHOULD** indicates a recommendation. Its negative form **SHOULD NOT** indicate an option that should not be supported.
signed CDA® package	A single compressed digital file archive containing a clinical document, optional packaged attachments and one or more eSignatures [NEHTA2011a].
SNOMED CT-AU	Systematized Nomenclature of Medicine Clinical Terms – Australia. SNOMED® and SNOMED CT® are registered trademarks of the International Health Terminology Standards Development Organisation.

Term	Meaning
Standing consent	The consent provided by a healthcare individual when they agree to the creation of an eHealth record in the PCEHR system. Standing consent allows any participating healthcare provider to upload health information to a healthcare individual's eHealth record. Standing consent continues to apply unless the healthcare individual explicitly withdraws their consent.
supporting organisation	An organisation that assists in the delivery of healthcare, but is not a healthcare provider organisation. Examples are registered repository operators, and registered portal operators.
supporting organisation registration number	A number that uniquely identifies a supporting organisation. The number has 16 digits, commences with '800364', and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
third-party	Third-party refers to a software system developed independently of the national PCEHR system and intended to connect to the national PCEHR system.

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