Australian Government
Department of Health

NPAAC TIER 3B DOCUMENT

REQUIREMENTS FOR INFORMATION COMMUNICATION AND REPORTING

(Fourth Edition 2020)

National PATHOLOGY ACCREDITATION Advisory Council

Print ISBN: 978-1-76007-420-3

Online ISBN: 978-1-76007-421-0

Publications approval number: DT0001906

Copyright

First published 1998	
Second edition 2007	reprinted with revisions and name change from *Guidelines for Data Communication*
Third edition 2013	reprinted and reformatted to be read in conjunction with the *Requirements for Medical Pathology Services*
Fourth edition 2020	reprinted with revisions

Australian Government Department of Health

Contents

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to advise the Australian, state and territory governments on matters relating to the accreditation of pathology laboratories. A key role of NPAAC is to develop and maintain pathology quality standards for accreditation. NPAAC also advises on pathology accreditation policy initiatives and initiates and promotes education programs about quality in the provision of pathology services.

Publications produced by NPAAC are issued as accreditation materials to provide guidance to medical pathology laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a potential risk to public health and patient safety.

Scope

The *Requirements for Information Communication and Reporting (Fourth Edition 2020)* is a Tier 3B NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services.* The latter is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

This document addresses communication of pathology information between pathology laboratories, requesters, consumers and other parties. It emphasises the role of the laboratory and defines the boundary of responsibility of the laboratory, recognising that a laboratory may be limited in its ability to influence requesting practitioners to implement desirable practices, although laboratories must address identified high risk scenarios.

Throughout these Requirements, processes which improve safety, security and privacy, and reduce the risk of harm to patients have been identified within the Standards and Commentary.

The structure and maintenance of databases, data for secondary transmissions, and retention of data are outside the scope of this document.

Abbreviations

Abbreviation	Description
APUTS	Australian Pathology Units and Terminology Standardisation
AS	Australian Standard
HL7	Health Level 7 Standards
HPI-I	Healthcare Provider Identifier - Individual
HPI-O	Healthcare Provider Identifier - Organisation
IHI	Individual Healthcare Identifier
ISO	International Organization for Standardization
LOINC	Logical Observation Identifiers Names and Codes
NPAAC	National Pathology Accreditation Advisory Council
SPRC	Structured Protocols for Reporting Cancer
PKI	Public Key Infrastructure
RCPA	Royal College of Pathologists of Australasia
SNOMED CT	Systematized Nomenclature of Medicine-Clinical Terms
SPIA	RCPA Standards for Pathology Informatics in Australia
UCUM	Unified Code for Units of Measure

Definitions

Term	Definition
Access audit trail	means a record of views of an individual's health record data without modification by people, recording (as a minimum) date, time, patient identifier and person viewing. Access to data performed regularly as part of routine operations may be recorded to a lower degree of specificity. (see also 'audit trail')
Application acknowledgment	means a computer generated acknowledgment by the receiving application confirming receipt and processing of data.
Audit trail	means a chronological sequence of human readable audit records, each of which contains evidence directly pertaining to and resulting from the execution of a business process or system function.
Authentication	means the process that verifies the claimed identity of a station, originator or individual as established by an identification process. Authentication ensures that the individual or organisation is who they claim to be. *Comment: Authentication of the origin of a message received from an alleged sender may be for example by means of direct telephone dial, virtual private network with password or with digital certificates (secure socket layer [SSL], or public key infrastructure [PKI]).*
Clinical acknowledgment	means a record of acknowledgment that a clinician has received and is taking responsibility for acting on results; this may be delivered by any means including phone, and clinical application acknowledgement.
Confidentiality	means limiting access to information to persons authorised to access, and/ or use documents or information that is considered private.
Edit audit trail	means a record of additions and alterations to an individual's health record, including (as a minimum) date, time, patient identifier, instrument and/or authorising person, and the nature of the edit.

Term	Definition
Electronic report	means a report message transmitted using computer or electronic device.
Electronic request	means a request message transmitted using computer or electronic device.
eRequesting	means submitting a pathology request through an electronic request.
Healthcare Provider Identifier–Individual (HPI-I)	means the unique identifier used to identify individual healthcare providers who deliver healthcare in the Australian healthcare setting.
Healthcare Provider Identifier-Organisation (HPI-O)	means the unique identifier used to identify organisations which deliver healthcare in the Australian healthcare setting.
Individual Healthcare Identifiers (IHI)	means the unique identifier used to identify individuals who receive or may receive healthcare in the Australian health system.
Integrity	means internal consistency or lack of corruption in electronic data.
Interoperability	means the ability of two parties, either human or machine, to exchange data or information in a manner that preserves shared meaning.
Message	means communication of requests and reports to and from an external party.
Patient	means an individual who is receiving pathology tests . Where the term 'patient' is used, this can also mean a consumer.
Report	means the provision of results, interpretation and opinions from a pathology request.
Request	means a requisition received to perform a test.

Term	Definition
Requirements for Medical Pathology Services (RMPS)	means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, Laboratory staff and referrers (both for pathology requests and inter-Laboratory referrals) are safely and satisfactorily met in a timely manner.
Security	means the defence of digital information and IT assets against internal and external, malicious and accidental threats. Weak security can result in compromised systems or data.
Secure messaging	means a core foundational capability required to enable interoperability and safe, seamless, secure, and confidential information sharing across all healthcare providers and consumers.
Structured reporting	means a report format which utilises standard headings, definitions and nomenclature with required information.
Synoptic reporting	means a structured report in condensed form (as synopsis or precis).
Third-party access	means access by a party other than the original requester.
Third-party enquiry	means a request by an entity other than the original requesting authority for a copy of a report(s). This is considered a 'directly related secondary purpose'.
Transport acknowledgment	means a computer or machine generated acknowledgment confirming delivery of an electronic message to a location; this ensures, to a reasonable degree of certainty, that a message has been successfully delivered, but does not ensure it has been processed correctly by a receiving application nor that a clinician has taken appropriate and timely responsibility to act; this applies equally to electronic messages and facsimile transmissions. (a facsimile transmission is not deemed successful until a transport acknowledgment is received). *Refer to Clinical acknowledgement and Application acknowledgement.*

Term	Definition
Transport layer security	means a protocol that provides authentication, privacy and data integrity between two communicating computer applications.
Urgent	means ‘requiring immediate attention’ as determined by the requesting practitioner or by the laboratory.

Introduction

The *Requirements for Information Communication and Reporting (Fourth Edition 2020),* is a Tier 3B standard and together with the *Requirements for Medical Pathology Services,* outline framework for the communication of pathology information within the Request-Test-Report Cycle.

These Requirements set out the minimum standards to ensure the integrity of patient information during the transfer of information with external parties. To manage potential risks, laboratories must be able to ensure the confidentiality, integrity (including authenticity) and availability (collectively known as information security) of messages received and sent to the authorised recipient. This includes recording, storing and, where required, archiving messages and the tracking of access and transmission of these messages.
The Standard has sought to identify the major risks to patient safety associated with information communications and sets standards to mitigate those risks.

Requirements have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization including:

AS ISO 15189 *Medical laboratories – Requirements for quality and competence*
AS/ISO 27799 ISO/DIS *Health informatics -- Information security management in health using ISO/IEC 27002*
AS5552 -2013 *– E-health secure message delivery*
AS4700.2 *Implementation of Health Level Seven Part 2: Pathology and Diagnostic imaging (diagnostics)*
AS 4846-2014 *Person and provider identification in healthcare*
ISO27001 & ISO27002 System security processes and methodologies

As this a rapidly changing technical environment, standards are likely to be under regular revision and change. Laboratories are encouraged to refer to current best practice standards. These Requirements should be read within the national pathology accreditation framework including the current versions of the following NPAAC documents:

All Tier 2 and Tier 3 Documents

In addition to these Standards, Laboratories must also comply with all relevant jurisdictional legislation.

In each section of this document, points deemed important for practice are identified as either 'Standards' or 'Commentaries'.

- A Standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a Laboratory can attain accreditation – Standards are printed in bold type and prefaced with an 'S' (e.g. **S2.2)**. The use of the word '**must**' in

each Standard within this document indicates a mandatory requirement for pathology practice.

- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Note that when comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached. Where a Commentary contains the word '**must**' then that commentary is considered to be **normative**.

Please note that any Appendices attached to this document may be either normative or informative and should be considered to be an integral part of this document.

Please note that all NPAAC documents can be accessed at
www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

The Secretary
NPAAC Secretariat
Department of Health
GPO Box 9848 (MDP 851)
CANBERRA ACT 2601

Phone: +61 2 6289 4017
Fax: +61 2 6289 4028
Email: npaac@health.gov.au
Website: www.health.gov.au/npaac

1. Governance

(Refer to Standard 1, Standard 2, Standard 3, Standard 4, Standard 5 and Standard 6 in *Requirements for Medical Pathology Services*)

Governance is a means of ensuring that the contents are delivered in a satisfactory manner.

This section is about information governance including privacy. Privacy principles must be maintained in pathology request and report communication.[*] Laboratories must have an understanding of the importance of laboratory information structures and have a risk based approach to managing assets. Refer to ***Appendix B***.

S1.1 The designated person[†] must ensure the governance of information communication is clear, appropriate and documented.

C1.1(i) If responsibility is assigned to another person within the organisation, the responsibilities **must** be documented.

C1.1(ii) Where any information communication functions are provided by a third party provider, the designated person **must** have completed a risk assessment to ensure that risks are managed and there are relevant agreements in place to demonstrate conformance with the necessary requirements.

S1.2 All forms of communication must undergo a risk assessment before being implemented or changed.

C1.2 Investigations of both data breaches and failures to transmit pathology results to the responsible persons should be used to review or update of the laboratory's risk assessment.

S1.3 The laboratory must document policies and procedures for the receipt of requests and transmission of reports.

C1.3 The documented policy **must** include:

(a) the roles and responsibilities of laboratory staff handling pathology requests and reports (including receipt and dispatch)

(b) details of standards and specific requirements relating to the confidentiality, authenticity, integrity and availability of electronic pathology reports and requests

[*] https://www.oaic.gov.au/privacy/australian-privacy-principles/australian-privacy-principles-quick-reference/

[†] Requirements for Medical Pathology Services

(c) access rights and controls, including details about what these are and who they relate to, in relation to transmission of electronic pathology reports and requests

(d) the processing of electronic request and electronic report message receipt acknowledgments

(e) storage and archiving requirements, including a record of the transmission of electronic pathology reports and requests

(f) procedures for internal audits to ensure all processes are operating in accordance with the management system.

S1.4 Incidents and adverse events related to information data breaches must be regularly reviewed with the intention of identifying the cause and mitigating the risk of further events.

C1.4 The effectiveness of these mitigants **must** be monitored and regularly reviewed.

S1.5 The laboratory must ensure the transmission and archiving of pathology messages are supported by trained staff who have been assessed to be competent.[‡]

S1.6 All staff must have received training in the awareness and treatment of cyber risks.

S1.7 All laboratories must have an information security management system, such as that described in ISO27000. [§]

[‡] Requirements for Medical Pathology Services – Standard 6
[§] ISO27000

2. Security of electronic communications

(Refer to Standard 1 and Standard 6 in *Requirements for Medical Pathology Services*)

This standard addresses the communication of the content. It sets out the expectations of the level of acknowledgment of the communication.

S2.1 For the secure messaging of electronic pathology requests and reports, the laboratory must ensure:

(a) the completeness, accuracy and integrity of electronic messages

(b) the pathology laboratory message can be authenticated by the recipient.

C2.1(i) Laboratories **must** have a risk based approach to ensuring the capability to transmit and receive messages.

C2.1(ii) The secure messaging protocol is supported by procedures to manage the authentication of the requestor and recipient of the message.

C2.1(iii) All communication protocols **must**:

(a) authenticate the originator of the pathology request

(b) acknowledge receipt of incoming messages (transport level and application level acknowledgement)

(c) authenticate the recipient of the pathology report at the initial setup.

C2.1(iv) Before first time transmission of results for SMS, email or faxed messaged reports to recipient, an authentication process **must** be performed and recorded before transmission of the result e.g. sending test message.

C2.1(v) The record of receipt of an electronic acknowledgment message is considered to be part of the electronic patient record.

C2.1(vi) Electronic report messages cannot be considered successfully delivered until a clinical application acknowledgment message has been received, confirming delivery. It is recognised that clinical software receiving report messages may not send an acknowledgment. However, software vendors should be encouraged to include this feature in their products.

C2.1(vii) Laboratory acknowledgment of an electronic request does not constitute a contract to undertake services; it indicates a willingness and capability to enter service agreements to perform or refer the requested services.

S2.2 There must be an acknowledgement of outbound communications.

C2.2(i) Laboratories **must** have a transport level acknowledgement to indicate that a message has been received. This is the minimum requirement under this Standard.

C2.2(ii) There **must** be a procedure for the transmission of high risk and urgent results which ensures this always occurs.

C2.2(iii) Laboratories should have application level acknowledgement. This is generated by the receiving application (e.g. clinical desktop solution) indicating that the message has been received and committed to secure storage for processing by an appropriate clinical application.

C2.2(iv) Laboratories should have a clinical level acknowledgement, where available. Given the high risk of the non-review of clinical data, a risk assessment of processes should be undertaken.

S2.3 The laboratory must have a procedure to deal with transmission failures in a timeframe relevant to clinical risk and requester expectations.

C2.3 A procedure **must** be in place for high risk and urgent results to ensure the effective communication of results and acknowledgement from a person because of the risk of transmission failures.

S2.4 The laboratory must define what data needs to be communicated to the recipients of high risk results.

C2.4 The information communicated to the recipient of a high risk result **must** include the following:

(a) identity of the notifier;
(b) identity of the patient tested;
(c) date and time that the sample was collected, where given;
(d) test that was performed;
(e) test result (with the units of measurement where relevant)
(f) reported applicable reference interval for the patient or clinical decision limit(s) for the test, and the offer of pathologist or scientist consultation.

S2.5 Whenever a message is transmitted via a public network, the patient identified clinical information must be encrypted to protect the confidentiality of data and prevent unauthorised access during transmission.

C2.5(i) Accepted transport security protocols, such as Transport Layer Security (TLS)[**] or public key encryption mechanisms such as Public Key Infrastructure (PKI) **must** be used. Use of secure messaging fulfils these requirements.

[**] https://tools.ietf.org/html/rfc8446

C2.5(ii) Encryption should be considered in private networks as part of information security risk management.

C2.5(iii) Unencrypted emails should not be used for identified clinical information without patient consent.

3. Patient and provider identification

(Refer to Standard 6 in *Requirements for Medical Pathology Services*)

There are many patient safety benefits associated with the best practice use of identifiers and terminology.

S3.1 The laboratory must return all identifiers received to confirm identity.

C3.1(i) The laboratory should include the IHI in electronic data exchange where the IHI has been provided by a requesting practitioner in electronic form.

C3.2(ii) Where a requesting practitioner does not provide the laboratory with an IHI, laboratories are encouraged to obtain the patient's IHI via the health identifier service or previous pathology requests. The laboratory should then use the IHI in electronic data exchange.

S3.2 In electronic data exchange, the laboratory must include the healthcare provider identifier (HPI-I) and organisation (HPI-O) where it has been provided by a requesting practitioner in electronic form.

4. Conformance with electronic messaging standards

(Refer to Standard 6 in *Requirements for Medical Pathology Services*)

Laboratories should have in place processes to adopt updated versions of these standards as they are published by HL7 Australia.

S4.1 Laboratories must use the HL7 Standard as defined by the HL7 V 2.4 as set out in HL7AUSD-STD-OO-ADRM-2017.1 the Australian Pathology Messaging - Localisation of HL7 Version 2.4 2017.

C4.1(i) Use of the HL7 standard **must** include testing that demonstrates appropriate use of codes for orderables and results as well as use of patient, provider and organisation identifiers in the messages in accordance with Standard 3 of this document as well as management of message acknowledgments in accordance with Standard 2.

C4.1(ii) When this HL7 Standard is updated in Australian Standards laboratories are required to move towards adopting the new version.

5. Communications audit trail

(Refer to Standard 3, Standard 4 Standard 5 and Standard 6 in *Requirements for Medical Pathology Services*)

S5.1 Laboratory staff who have access to electronic pathology data and the ability to trigger transmission, change or correction of electronic data must use their own individual secure logins.

S5.2 If a paper request is received, then a scanned, hard copy or the original request must be stored keeping all the original content, date, time, location and originator of the request.

C5.2(i) The same information provided in electronic requests **must** also be stored.

C5.2(ii) Any changes to the request **must** be stored as well as the original.

S5.3 When an acknowledgment is received from any transmission (including interim reports), mode of result transmission must be recorded.

C5.3(i) The audit record **must** include:

(a) request registration

(b) patient identifier transmissions

(c) results entry and comments

(d) results transmission (e.g. date, time and mode)

(e) patient result access by non-laboratory staff. Alternatively, where it is deemed impractical to include access by such staff into the audit trail then such staff must have received adequate training in the area of jurisdictional privacy legislation

(f) a record of any subsequent changes to a previously validated report.

(g) key patient demographic changes including at least name, sex and date of birth.

5.3(ii) If results are amended, then the audit trail **must** support the collection of all of the above for the subsequent transmission.

S5.4 Laboratories must have procedures for the re-transmission of amended results.

C5.4(i) Mode of transmission includes printing, faxing, email and electronic transmission. It also includes verbal reporting by phone.

C5.4(ii) Laboratories **must** record the transmission of results by phone in response to result enquiries.

C5.4(iii) The audit record is considered part of the patient record.

C5.4(iv) Current paper-based and intra-laboratory systems provide for traceability of requests, technical procedures, results and reports. These capabilities

must be maintained and enhanced in electronic systems, so that access, actions and changes can be traced where and when necessary.

S5.5 The laboratory collecting the audit trail information must notify its staff (and any other parties who access patient records):

(a) that their access to patient records will be recorded on the audit trail

(b) what personal information is collected (i.e is it just their name) and a link to the relevant privacy policy of the laboratory that is collecting and disclosing the personal information

(c) of the purpose and use of the audit trail information

(d) to whom the audit trail information may be disclosed.

6. Request and report format requirements

(Refer to Standard 6 in *Requirements for Medical Pathology Services*)

Standardised terminology contributes to patient safety. The format that results are reported can have a significant impact on the way they are interpreted. Differences in reporting formats between laboratories can lead to confusion and misinterpretation. Key requirements for reports are outlined in ***Appendix A.***

S6.1 Where the SPIA standard is not used, laboratories must undertake a risk assessment that provides assurance for patient safety, in addition to the provision of a list of systems used and reasons.

S6.2 A laboratory must ensure that at least one of the observational identifiers used in an electronic report should use the SPIA LOINC coding system, where available, and the associated UCUM units that is in accordance with the SPIA Standards[4] when sending to external organisations.

C6.2(i) The source of LOINC codes should be those specified in SPIA.[4]

C6.2(ii) If SNOMED codes are used in messages, laboratories should use the SNOMED CT AU code set.

C6.2(iii) A laboratory may use non-LOINC observational identifiers.

S6.3 The content and format for cancer reporting must be in accordance with the National Structured Pathology Reporting Protocols. [2]

C6.3(i) Published guides for the implementation of Structured Reporting incorporate a tabulated matrix for different levels of sophistication in reporting. Level 1-3 relate only to the content and format of a report, all within a single text field. Levels 4-6, in addition, detail progressive levels of electronic implementation.

C6.3(ii) Level 3 reporting improves the completeness and clarity of cancer reports and requires only that the content complies with the available NSPRC published datasets and that a structured or synoptic format is used. [2]

C6.3(iii) Level 3 reporting is achievable by all laboratories in Australasia without additional infrastructure or cost and **must** be the minimum level of compliance for reporting of cancers for which published protocols exist.

Appendix A Report Format Requirements (Informative)

This appendix is based on the RCPA *Standards for Pathology Informatics in Australia.*[4] Laboratories should adopt these standards but in circumstances where this is not achievable a risk assessment should be conducted. This should determine what is the likely risk and consequence of that risk and whether effective mitigation strategies can be introduced until the standards are met.

A. Terminology

The standardisation of pathology terminology and units in Australia is desirable and achievable.

A1 Principles

A1.1 No single existing terminology is sufficient.

A1.2 Having well-developed subsets of terms will improve conformance, compliance and efficiency.

A1.3 A high level of knowledge and familiarity with the practice of pathology is required to develop and maintain these subsets.

A1.4 The terms used in Australia will reflect common usage and will be consistent and safe.

A1.5 The terms will be practical and capable of ready implementation.

A1.6 All standardised pathology terminology and associated units will be available in one place.

A1.7 SNOMED should be used as the preferred terminology for requesting pathology.

A1.8 LOINC should be used as the preferred terminology for the highest level test name in reporting pathology.

A1.9 A rendering of the pathology report as the issuing laboratory intends it to be read, should be sent by the laboratory in all electronic messages. Receiving systems should be able to conveniently display this rendering to the reader for review if it is not used as the primary form for display.

A1.10 Combining data for a subject from what appears to be the same test in a time series such as in cumulative reports or graphs, carries with it significant clinical risk of misinterpretation and should only be done after that risk has been properly assessed and in accordance with the guidance provided here.

A1.11 The risk of combination referred to above means caution is required when grouping results from different laboratories, methods or times for research or other statistical purposes.

B. Reporting terminology and codes

B1 Principles

B1.1 A reference terminology set for result names (the question) for each of the disciplines is available[4]:

- Anatomical and cytopathology
- Chemical pathology
- Genetic pathology
- Haematology
- Immunopathology
- Microbiology

B1.2 The context for the use of result name terms (the questions) where the result reported is not a simple question-answer construct is described in information models.

B1.3 In some cases reference sets for terms used as results (the answers to the questions, for example terms and codes for pathogens) have also been created[4].

B2 Implementation

B2.1 Where a code is used to identify a term for electronic communications it should be the code that appears associated with the term in the reference set.

(i) Where no such term or code is available a local code may be used provided it is identified as such in the message.

(ii) Where no code is available a request for a new code should be made. A temporary code will be issued and that should be used in the interim.

B2.2 Electronic pathology reports should use information models, coded test name concepts and preferred terms from the materials referenced here.

(i) Where no appropriate term is available free text may be used to describe the test.

C. Tests not to be combined in reports

C1 Principles

There are some tests for which it is both inappropriate and unsafe to compare results between laboratories and/or over time. This can be due to different methods being used, changes to reagents for the same method and/or different clinical conditions.

For safe interpretation of these results it is important that there be an indication with the result for the receiving system if it is unsafe to make these comparisons. The primary way of doing this is with the terminology. When developing the reference sets if methodology was considered to warrant a different reference interval then method dependant codes were assigned. This means that the one test name may have more than one code associated with it. The choice of code is the principal way by which a 'do not combine' signal is conveyed. Results **must** not be combined if they have different LOINC codes.

Test coding alone, however, is not sufficient to identify all of the cases where it would be inappropriate to combine results. As a result a secondary flag and associated coding system was developed to indicate whether it could be safe for tests from different laboratories or from the same laboratory over time to be reported on the same line in a cumulative report or as points in the same line on a graph. The flag for this purpose is called the 'Combining Results Flag'.

Values for the Combining Results Flag, their meaning and the expected action are given below:

Table 1: Values for the Combining Results Flag

Green	This test is considered safe to combine if harmonised Combine (with caution)
Orange	This test has either not yet been considered or there is uncertainty around comparisons Do not combine
Red	This test is known to be unsafe to make comparisons Do not combine

The Combining Results Flag values for tests where they have been determined are included in the terminology reference sets.

C2 Implementation

C2.1 Tests that have method-dependent terms and codes in the terminology reference sets **must** have the appropriate code applied.

C2.2 Tests that have the same LOINC code, but different units e.g. umol/L and mmol/L, **must NOT** be shown as the same test in sequential display whether by graph or cumulative reporting.

C2.3 Tests that have different LOINC codes **must NOT** be shown as the same test in sequential display whether by graph or cumulative reporting.

C2.4 Tests that have a 'Combining Results Flag' with the value of 'Red' or 'Orange' **must NOT** be shown as the same test in sequential display whether by graph or cumulative reporting if they come from different laboratories.

D. Preferred terms

D1 Principles

D1.1 The preferred term is the term preferred for use for the test in Australia for display on paper reports or screens. The test is fully described by the corresponding fully defined name from either SNOMED (for requesting) or LOINC (for reporting).

D1.2 The rules for establishing preferred terms apply for requesting and reporting. Many of the rules are aimed at ensuring safe rendering of the names by various devices and in different circumstances. As an example, the use of special characters such as Greek letters, symbols, super and subscripts that may not be able to be rendered by some devices can lead to misinterpretation and so are ruled against. There is also a general aim to remove redundancy and make the most important element of a name come first.

D2 Implementation

D2.1 Where there is no preferred term available for a test in the reference sets, free text descriptions should conform to the conventions used in developing preferred terms as described here.

E. Units of measure

E1 Principles

E1.1 The standardisation of units used for reporting pathology in Australia is desirable and achievable.

E1.2 All standardised pathology terminology and associated units should be available in one place.

E1.3 A single, test-specific, standardised unit of measure is preferred for use in reports from pathology laboratories.

E1.4 Units should be represented in electronic messages in such a way that receiving systems can readily convert units under the clinical governance of the receivers.

E1.5 The Unified Code for Units of Measure (UCUM) is to be used as the logical representation of units of measure in electronic messages.

E1.6 Numeric results should always have the appropriate units associated with them and they must never be displayed without them.

E2 Implementation

E2.1 Units of measure **must** always be shown where a quantity is shown on pathology reports.

(i) The exception is where it is explicit that no units are used for a particular test such as *Human chorionic gonadotropin qual.*

E2.2 Pathology reports should use the units specified in this document for those tests where units have been determined.

E2.3 A single, standardised unit of measure should be used for tests in reports from pathology laboratories.

(i) There may, however, be valid exceptions to this rule;

(a) in a transition from one preferred unit to another

(b) where alternate units are required by legislation or regulation such as for a registry

(c) during a period of consensus building as to which will be the preferred unit, but this period should be a short as is practical

(d) where a facsimile of an historic report is produced – historic data need not comply.

E2.4 Units should be represented in electronic messages in fields for units in such a way that receiving systems can readily convert units under the clinical governance of the receivers. The Unified Code for Units of Measure (UCUM) should be used where it is the intention to represent units in a computable form (see http://unitsofmeasure.org/).

E2.5 Where the unit is not specified here, UCUM should be used for the unit. UCUM lexical elements such as square brackets ('[' and ']') can be removed in the display format for enhanced clarity. However, the fully defined UCUM syntax should be used in electronic messaging.

E2.6 The caret symbol (^) should be used to represent "raised to a power of". Care must be taken to appropriately "escape" the caret symbol (^) as this symbol is used as a component separator in HL7 messages.

E2.7 Units raised to a power should be indicated in the preferred display unit by the exponent as an integer number written immediately behind the unit term. For example, the preferred display unit for millilitre per minute per 1.73 square metre is mL/min/1.73m^2. Powers of ten should be represented by 10^ e.g. 10^12/. Display example: mL/min/1.73m^2, 6.1x10^12/L; Message example: ml/min/1.73m\S\2, 6.1x10\S\12/L.

F. Rendering of numeric results, ranges, units, previous results and flagging

F1 Principles

F1.1 Numeric results are incomplete without associated units and guidance for interpretation (e.g. reference intervals) and so these **must** always be shown with the number.

F1.2 Further interpretation of results over time depends on knowing the latest results (and the direction of time) therefore when results are shown in columns, rows or graphically these should be consistent across disciplines and laboratories and the latest results must be differentiated from previous results.

F1.3 Changes to configuration in the rendering of a report should be thoroughly tested in both printed and electronic format to ensure the report is displayed as intended by the receiver.

F1.4 The rendering of the pathology report as the issuing laboratory intends it to be read should be sent by the laboratory in all electronic messages and be able to be displayed to the reader on screen or printed out.

F1.5 When reports are displayed on screen the latest results should be shown on the first display screen to avoid any chance of missing a latest result column or row that is off-screen.

F1.6 Because around 4.5% of the population are colour blind and because some methods of communication remove colour, colour should **not** be used as the only method for highlighting.

F1.7 Multi-level flagging may be used.

F2 Implementation

An example of the application of the standards and guidelines for report rendering is shown for a columnar cumulative report in Figure 3 on page 39 of the *Australian Pathology Units and Terminology Standards and Guidelines (V2.2)*.*

F2.1 Numeric results should be right justified (when shown in columns) and have corresponding guidance values (eg reference interval) and units if these exist.

F2.2 Numeric results should have a leading zero where there is no number in the units place (i.e. 0.7 not .7).

F2.3 For columnar cumulative reports the latest result should be shown in the furthest right column of results (i.e. time must go from left to right across the page) or at the top for cumulative reports shown in rows (i.e. time must go from the bottom to the top of the page).*

F2.4 The latest result should be differentiated from earlier results by at least two methods one of which is a heading 'Latest Results'.

(i) A box such as that shown in Figure 3 was favoured by 75% of survey respondents for columnar reports.

(ii) Bolding of the heading text was considered effective by the Committee.

F2.5 Guidance values should be bounded by parentheses and have no spaces.
(i) Italics should not be used.

F2.6 The column showing units should be headed 'Units', be left justified and be to the immediate right of the 'Reference' column.

F2.7 The numbers used for guidance should be rendered with the same number of decimal places as the related result.

(i) For some analytes, such as tumour markers, a result may be orders of magnitude above guidance in which case current practice for some laboratories is to adjust for significant figures because of concern at overstating precision. It is not known whether it is safer to do this or to adopt the number of decimal places for the low range result. If a different number of decimal places is used at different concentrations, the guidance should be rendered to the same number of decimal places as the results of a similar magnitude to the guidance values.

F2.8 Results are considered outside the guidance values if after rounding to the format of the displayed result (and the guidance) the result is greater than the higher number or less than the lower number of the guidance values.

F2.9 Results outside the guidance values should be highlighted by at least two methods one of which is either an 'L' or 'H' one space to the right of the result ('L' for a result lower and 'H' for a result higher).

(i) A single asterisk ('*') and the '+' and '-'characters should **not** be used for flagging results.

(ii) Underlining of results should not be used for highlighting results.

(iii) Colour was preferred by most respondents in the survey but because of colour blindness and possible loss of colour in some communications, if colour is used, then the font should also be bolded.

(iv) Multi-level flagging may be used in which case 'LL' or 'HH' should be used for the second level.

F2.10 Headings should be differentiated from test names.

F2.11 Dates should be shown in the form 30-Jan-14 (i.e. not in the form 30/01/14).

G. Harmonised reference intervals

A set of harmonised reference intervals for reporting pathology in Australia (and New Zealand) is available at the RCPA website.[4] These reference intervals are by age and sex where appropriate and include values used in paediatrics.

G1 Principles

G1.1 Guidance values should be evidence based but as simple and consistent as real biological variation and good medical practice allows.

G1.2 Because common usage for analyte reference limits has both the low and high values included while for age limits the higher value is not included, to avoid any confusion in interpretation of boundary conditions these need to be represented in different ways in reports and tables used outside the laboratory.

G1.3 There is as yet no international standard for representing age intervals and the committee proposes the format '1w to <12y' to show the time interval in a table or on a report. This was done to avoid confusion on reading and with the meaning of mathematical notation.

G1.4 The same method for representing age intervals should be used for adults and children.

G2 Implementation

Where reference intervals other than those provided here are used, laboratories should document their reasons and the evidence that alternate intervals are preferable.

G2.1 Age intervals are calculated in days from date of birth to date of collection starting with day 0 being the day of birth with the result always rounded down.

G2.2 Age intervals should be rendered using days, weeks or years (but not months)*[4]. The Table also provides the interpretation of time ranges for common age intervals.

(i) A mixture of days, weeks and years is permissible where it is appropriate (eg '7d to <10y').

Table on page 45 of the Australian Pathology Units and Terminology Standards and Guidelines (V2.2)

Appendix B Online versions of national, state and territory privacy legislation (Informative)

National

Privacy Act 1988
http://www.privacy.gov.au/publications/privacy88_030706.pdf
National Privacy Principles
http://www.privacy.gov.au/publications/npps01.pdf
Privacy (Private Sector) Amendment Regulations 2006 (No. 1) Statutory Rules No. 301
http://www.privacy.gov.au/publications/2006no1reg.pdf

Australian Capital Territory

Health Records (Privacy and Access) Act 1977
http://www.legislation.act.gov.au/a/1997-125/current/pdf/1997-125.pdf

New South Wales

Privacy and Personal Information Protection Act 1998
http://www.austlii.edu.au/au/legis/nsw/consol_act/papipa1998464
Health Records and Information Privacy Act 2002
http://www.austlii.edu.au/au/legis/nsw/consol_act/hraipa2002370

Northern Territory

Information Act 2002
http://www.nt.gov.au/nreta/foi/infoact.html

Queensland

Information Standards 42A (Health)
http://www.governmentict.qld.gov.au/02_infostand/standards/is42a.pdf

South Australia

Information Privacy Principles 1989
http://www.premcab.sa.gov.au/dpc/publications_circulars.html

Tasmania

Personal Information Protection Act 2004
http://www.egovernment.tas.gov.au/themes/information_security__and__management/personal_information_protection

Victoria

Information Privacy Act 2000
http://www.dms.dpc.vic.gov.au/Domino/Web_Notes/LDMS/PubLawToday.nsf/0/b1a1dfc4eebe1eeaca256e5b00037a1d/$FILE/00-98a001.pdf
Health Records Act 2001
http://www.health.vic.gov.au/healthrecords

Western Australia

Health Act 1911
http://www.newpublichealthact.health.wa.gov.au/home
Please note: at the time of publication there was no state-specific privacy legislation in Western Australia.

References

1. Attorney-General's Department, *Privacy Act 1988,* Attorney-General's Department, Canberra, 1988, viewed 3 July2019, <https://www.legislation.gov.au/Details/C2020C00168>

2. Royal College of Pathologists of Australasia, *National Structured Pathology Reporting Protocols* , Royal College of Pathologists of Australasia, 2013, viewed 3 July 2019 <https://www.rcpa.edu.au/Library/Practising-Pathology/Structured-Pathology-Reporting-of-Cancer>

3. Royal College of Pathologists of Australasia, *Standards for Pathology Informatics in Australia*, viewed 3 July 2019 <https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/APUTS-Downloads/Standards-and-Guidelines>

4. Royal College of Pathologists of Australasia, *Position Statement: Structured Pathology Reporting of Cancer - Incorporating a Level 3 Implementation Guide (Number 2/2015)*, Royal College of Pathologists of Australasia, May 2019, viewed 3 July 2019 <https://www.rcpa.edu.au/getattachment/5cdebb47-9308-442a-91c8-22cdd4b93290/Structured-Pathology-Reporting-of-Cancer.aspx>

Bibliography

Standards Australia. AS 5552-2013 E-health secure message delivery. Australia: Standards Australia, 17 December 2013. 110 p.

Standards Australia. AS 4700.2–2004 Implementation of Health Level Seven (HL7). Australia: Standards Australia, 19 March 2004. 70p.

Standards Australia. AS 5017-2006 Health Care Client Identification. Australia: Standards Australia, 30 June 2006. 119p.

Standards Australia. AS/NZS ISO/IEC 27002:2006 Information technology - Security techniques - Code of practice for information security management. Australia: Standards Australia, 6 July 2006. 116p.

Standards Australia. AS/NZS ISO/IEC 17799:2001 Information technology – Code of practise for information security management. Australia: Standards Australia, 8 June 2001. 71p.

Standards Australia. HB 262-2002 Pathology electronic messaging - Guidelines for pathology messaging between pathology providers and health service providers - Implementation guide. Australia: Standards Australia, 20 June 2002. 125p.

Standards Australia. HB 262-2012 Guidelines for messaging between diagnostics providers and health service providers. Australia: Standards Australia, 14 February 2012. 125p.

HB262-2012 is directed at HL7 v2.4, it is also applicable to HL7 v2.3.1

<http://www.e-health.standards.org.au/> viewed on 3 July 2019

National eHealth Transition Authority. NEHTA-1732:2014 Use of HIs in Health Software Systems - Conformance Requirements v3.1. Australia: NEHTA, 31 October 2014.

Acknowledgements

Dr Michael Harrison **(Chair)**

Professor Frank Bowling

Ms Melissa Cadzow

Mr Paul Carroll

Professor Andrew Clousten

Mr Derek Holzhauser

Dr Graham Jones

Mr Peter Joseph

Associate Professor Beverley Rowbotham AO

Ms Gillian Treloar

Professor Roger Wilson

Members of the NPAAC Document Review and Liaison Committee

Members of the National Pathology Accreditation Advisory Council

Further Information

Other NPAAC documents are available from:

NPAAC Secretariat	Phone:	(02) 6289 4017
Diagnostic Imaging and Pathology Branch	Fax:	(02) 6289 4028
Department of Health	Email:	npaac@health.gov.au
GPO Box 9848 (MDP 851)	Website:	www.health.gov.au/npaac
CANBERRA ACT 2601		

This page is intentionally blank

REQUIREMENTS FOR INFORMATION COMMUNICATION AND REPORTING

(Fourth Edition 2020)

DT0001906 July 2021

www.health.gov.au/npaac

All information in this publication is correct as at July 2021