SA Health

CMV Seronegative Blood Components for Clinical Use Clinical Guideline

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Government of South Australia
SA Health

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Contents

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1. Name of clinical guideline

CMV Seronegative Blood Components for Clinical Use

2. Introduction

South Australian[1] and national stewardship directives[2], along with National Safety and Quality Health Service Standards[3] (Standard 7) require Health Services to implement policies, procedures, guidelines and strategies to ensure safe and appropriate transfusion practice.

This guideline sets out the patient groups for whom transfusion with Cytomegalovirus (CMV) seronegative blood components/products is clinically indicated and supported by evidence, where available. It also establishes criteria for holding CMV seronegative blood components across SA Health based on the SA Health Clinical Services Capability Framework[4].

There are significant logistics (and associated costs) in the provision of the limited supply of CMV-N products, over and above the supply of standard leucodepleted products. Although intended for use within SA Health, private hospitals and pathology providers should seek to adopt this **guideline** to ensure optimal clinical use of CMV-N products in South Australia.

3. Background

What is CMV?

- Cytomegalovirus (CMV) is a common infection and easily acquired in the community, transmitted through bodily fluids (including blood) or postnatally through breastfeeding. In healthy individuals CMV infection is often asymptomatic or a mild non-specific illness. However, it may cause life threatening disease in susceptible groups, such as immunosuppressed individuals and neonates. Congenital infection may also occur with primary maternal infection in pregnancy[5].
- After contracting CMV, individuals who recover from the infection become CMV seropositive approximately 6-8 weeks later. They remain potentially infectious for life due to dormant (latent) infection primarily in mononuclear white cells and their precursors.[5]
- Where practitioners are concerned about the risk of CMV transmission, they should educate patients regarding risks of community transmission, and simple precautions to reduce risk especially for pregnant women and mothers of newborn babies[5].

How is the risk of transfusion transmitted CMV reduced?

- Transfusion of CMV seropositive blood components can give rise to primary infection in CMV negative recipients. Seroselection (CMV antibody screening) of donors and leucodepletion are the two main strategies for prevention of transfusion transmitted CMV (TT-CMV). Universal pre-storage leucodepletion of red cells and platelets was implemented in Australia in 2008 and leucodepleted red cells and platelets are now the standard products issued by Australian Red Cross Lifeblood. Although these two strategies for 'CMV-safe' products significantly reduce the risk of transmission, neither is 100% effective, however the risk remains many orders of magnitude less than community transmission[5]. It is unknown whether CMV-N blood products provide significant additional protection over routine leucodepletion. Since the introduction of leucodepletion, the optimal strategy for managing CMV-safe inventories has been debated. Seed et al estimated the residual risk of leucodepleted-only products in Australia is negligible (1 in 13 575 000).[6] This risk is very low compared to the risk of acquiring CMV in the community. See Appendix 2 for further information.

4. Summary of Indications for Clinical Use of CMV Seronegative Blood Products

- Noting the lack of international consensus, the South Australian Blood Management Council supports the use of the UK SaBTO[7], [8] recommendations for the use of CMV seronegative blood components (2012), which also underpins the ANZSBT guidelines (2020)[10]. Appendix 1 provides detailed recommendations.

Table 1: Summary of indications for use of CMV seronegative blood components (Also see Appendix 4):

Patients who require CMV seronegative cellular blood products
> CMV Seronegative products should be used for the following clinical indications: > pregnant women regardless of CMV status who require regular elective transfusions during pregnancy (but not during delivery) o intrauterine transfusion (IUT) o neonates (up to 28 days post expected date of delivery) o granulocyte transfusions for CMV negative patients. *In urgent situations, if CMV seronegative products are not available then leucodepleted products of unknown CMV status should be used to avoid delays*
Patients for whom leucodepleted blood products may safely be used
> Leucodepleted blood products are considered suitable for use (i.e. CMV safe) in the following situations: > solid organ transplants o haemopoietic stem cell transplants (HSCT; all adult and paediatric HSCT patients) o haematology and oncology patients o immunodeficient patients, including those with human immunodeficiency virus (HIV). > Institutions should consider whether to introduce polymerase chain reaction (PCR) monitoring for CMV for at-risk patients to allow early detection of any possible CMV infection.

5. Definitions

ANZSBT: means The Australian and New Zealand Society of Blood Transfusion.

CMV: means Cytomegalovirus.

CMV-N: means CMV IgG seronegative.

Leucodepletion: means Removal of white cells through filtration (done 'pre-storage' at time of manufacture in Australia). The term leukoreduction (LR) is used in some references.

SaBTO: means Advisory Committee on the Safety of Blood, Tissue and Organs.

SLS: means Safety Learning System

6. Prinicples of the standard

Current approaches to providing CMV-safe cellular blood components for transfusion vary around the world. There is a paucity of data to inform a meaningful conclusion about the optimal strategy. The incremental benefit of providing CMV-N components in addition to leucodepletion in the prevention of CMV transmission is unknown. Available guidelines are based on expert opinion.[16]

In 2012 the UK Department of Health's Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Report[7] and Position Statement[8] recommended that solely leucodepleted blood be considered sufficient risk reduction for TT-CMV in high-risk patient populations with the exception of intrauterine transfusion recipients, pregnant women and neonates who should be transfused with CMV-N products. This position statement was formed after review of evidence by an expert group (based on expert opinion, non-graded).

The SaBTO indications were more restrictive than clinical practice in Australia at the time but they were supported as the highest priority indications in a 2013 national Australian consensus statement9 for provision of CMV-N blood components to be applied during periods of constrained supply.

The ANZSBT 'Guidelines for transfusion and immunohaematology laboratory practice' (2020)[10] included the restrictive SaBTO indications in a section on CMV seronegative cellular blood products and patients who require them.

The national Patient Blood Management Guidelines in Australia: Module 5 - Obstetrics and Maternity (2015) and Module 6 - Neonatal and Paediatric (2016) include expert opinion points (not based on systematic review of the evidence) related to CMV-N blood products. These were largely consistent with the UK SaBTO indications but with the broader inclusion of paediatric haemopoietic stem cell transplant (HSCT) and severe combined immunodeficiency (SCID) as indications.[11,12] Module 3 - Medical (2012), however, did not include expert opinion points on indications for CMV seronegative blood products in adults.

International approaches vary. The AABB CMV Prevention Work Group commissioned a systematic review to develop clinical practice guidelines. However, the members concluded that the data was of poor quality, and no studies of significant size had been performed for over a decade. This resulted in the committee producing a report (published in 2016) rather than developing guidelines that would be of questionable utility. The group noted the wide variation in practices and that it was unlikely future large-scale clinical trials would be performed to determine whether leucodepletion, CMV-serology, or a combination of both is superior.[13]

In contrast, Canada's National Advisory Committee on Blood and Blood Products recommended in 2017 that CMV safe (leucodepleted) and CMV IgG seronegative products be considered equivalent except for intrauterine transfusion.[14]

Appendix 3 contains a comparison of Australian and International guidelines for a range of patient groups / indications that may be considered for use of CMV seronegative blood products. Many guidelines were developed before modelling regarding the residual risk of transfusion transmitted infection was estimated (see Seed et al[6]).

7. Determing risk factors

Specific risk factors attributable to transfusion with CMV seropositive blood components in specific patient groups have been outlined in Appendix 1.

Mechanisms must be in place for appropriate and timely communication for information regarding transfusion special requirements. Robust systems for noting patients' special requirements should be developed.

There are no additional clinical risks to patients not in the specific groups above receiving CMV seronegative blood components; however, this will pose a risk to inventory availability should these products be provided unnecessarily to these patients.

8. Models of care

The requirement for CMV seronegative components must be documented in the patient medical record and communicated to the transfusion service and patient / carers.

9. Workforce implications

Institutional education programmes and policies should be developed for treating clinicians, emergency department staff, nursing staff and pathology and blood bank staff to ensure adherence to this Guideline.

10. Safety, quality and risk management

> National Safety and Quality Health Service Standards (second edition)

 National Standard 1 Clinical Governance	 National Standard 2 Partnering with Consumers	 National Standard 3 Preventing & Controlling Healthcare-Associated Infection	 National Standard 4 Medication Safety	 National Standard 5 Comprehensive Care	 National Standard 6 Communicating for Safety	 National Standard 7 Blood Management	 National Standard 8 Recognising & Responding to Acute Deterioration
☒	☒	☐	☐	☐	☐	☒	☐

All incidents, including transfusion-transmitted CMV infections, should be reported via the SLS system. This includes 'near-misses', such as when non CMV-N components are transfused to high-risk patients.

Health Service organisations should undertake audits or compliance reviews to ensure this Guideline is implemented and laboratories should also consider auditing their requests for CMV seronegative blood components to monitor compliance.

11. Pathway / protocol

The transfusion service provider is responsible for recording the patients' special requirements in the laboratory information system.[15]

The clinician requesting the crossmatch or blood product is responsible for ensuring CMV seronegative components are requested for appropriate patients. It is the clinician's responsibility to ensure that accurate clinical information appears on the request form.[10]

The special requirements must also be documented as an alert in the medical record, as well as on the prescription each time the product is prescribed. The blood product checking procedure must ensure the blood product is checked for compliance with any special requirements on the prescription.[15]

12. Eligibility criteria

- **Inclusion**
  - Only sites providing a Level 5 or Level 6 Maternity or Neonatal Service[4] should hold inventory of CMV seronegative blood components. These sites have comprehensive blood and blood product services 24 hours per day, seven days a week.
- **Exclusion**
  - All other laboratories (not fulfilling the inclusion criteria) should not request CMV seronegative products for inventory.

13. Implementation and monitoring

Clinical Guideline has been implemented previously.

Haemovigilance data through the Safety Learning System will be monitored to ensure the clinical guideline has been implemented successfully in each Local Health Network. Blood, Organ & Tissue Programs will monitor laboratory ordering practices in liaison with Australian Red Cross Lifeblood to inform future education and training.

Laboratories should also consider auditing their requests for CMV seronegative blood components to monitor compliance.

14. Appendices

Appendix 1: Extract from the SaBTO Steering Group Report and Position Statement [7,8]

1. Groups at risk of transfusion-transmitted CMV

The following patient groups are at risk of transfusion-transmitted CMV; CMV seronegative haematopoietic stem cell and solid organ transplant recipients (receiving CMV negative transplants), patients with malignant disease, low birth weight and/or premature neonates of CMV seronegative mothers, foetal transfusion recipients, foetuses of pregnant (CMV seronegative and seropositive) women.

2. SPECIFIC PATIENT GROUPS

2.1. Haemopoietic stem cell transplant patients – adults and paediatrics

Rates of CMV transfusion-transmitted infection have been very low with both leucodepletion and serology screening, and the two techniques are probably equivalent. With both approaches there is likely to be a low failure rate. CMV monitoring and early effective therapy may however be a successful strategy for mitigating against the potential clinical effects. The routine use of CMV quantitative PCR/pre-emptive therapy (eg with ganciclovir or valganciclovir) in the setting of stem cell transplantation has significantly reduced the mortality from CMV infection overall (even in transplants involving seropositive recipients and/or donors). The mortality from other viral infections (eg respiratory viruses), bacterial and fungal infections far exceeds that of CMV in current transplant practice.

- *CMV seronegative red cells and platelets may be replaced with leucodepleted blood components for adults and children post haemopoeitic stem cell transplantation, for all patient groups including seronegative donor/seronegative recipients.*
- *Patients requiring transfusions who may require a transplant in the future may also safely be transfused with leucodepleted products (eg seronegative leukaemia or thalassaemia patients).*
- *CMV PCR monitoring should be considered for all patients (even CMV negative/negative patients) to allow early detection of any possible CMV infection (whether transfusion-transmitted or otherwise acquired).*

2.2. Neonatal patients

Given the potential severity of the consequences of CMV infection in this patient group, and the difficulty in monitoring neonates for infection (preventing pre-emptive therapy), it was considered to be important that leucodepleted and CMV seronegative blood components should continue to be provided.

- CMV seronegative red cell and platelet components should be provided for intra-uterine transfusions and for neonates (i.e. up to 28 days post expected date of delivery).
- All small sized blood packs and other cellular blood components intended for neonates should be provided as CMV seronegative.

2.3. Pregnant patients

As CMV seropositive women are at risk of reinfection and vertical transmission of the newly-acquired CMV strain, CMV negative blood components should be requested for all repeat elective transfusions during pregnancy, regardless of maternal CMV serostatus. This will avoid the need to determine maternal CMV status.

- *CMV seronegative red cell and platelet components should be provided for those requiring repeat elective transfusions during pregnancy (not during delivery).*
- *If, in an emergency situation, it is not possible to provide CMV negative blood products, leucodepleted products of unknown serostatus may be used.*

2.4. HIV and immunodeficient patients

No relevant literature was found regarding HIV and CMV. Due to the modes of HIV transmission, virtually all individuals with HIV infection also have CMV infection. With routine antenatal HIV testing, vertical transmission is now rare, and infants with HIV infection usually already have CMV infection. The mainstay of CMV infection management is control of HIV infection, and effective treatment is available for CMV disease.

- *No relevant literature was found that supported the use of CMV seronegative blood for immunodeficient patients.*
- *These patients should receive leucodepleted blood.*

2.5. Organ transplant patients

There is no published evidence of transfusion-transmitted CMV infection that would support the use of CMV seronegative blood for transplant patients. Testing of recipients and monitoring of outcomes is needed to provide more data in this area.

- *Organ transplant patients do not need to receive seronegative blood and should receive leucodepleted blood.*
- *Individual units should consider whether or not a policy of CMV PCR monitoring for some groups of patients (even CMV negative/negative patients) should be introduced to allow early detection of any possible CMV infection (whether transfusion-transmitted or otherwise acquired).*

2.6. Granulocyte components

Granulocyte components should continue to be provided as CMV seronegative for CMV seronegative patients. Granulocyte components cannot be leucodepleted.

Appendix 2: Extract from Clinical Use of Cytomegalovirus Seronegative Blood Products in Australia (2017)[5]

CMV is a common infection and one that is easily acquired in the community setting. In immunocompromised individuals, CMV infection can be devastating; however, this has become less of a problem partly due to selection of seronegative donors and leucodepletion as core strategies to prevent TT-CMV. The optimal strategy for managing CMV-safe inventories has been debated since the introduction of leucodepleted blood products in many countries. Newer diagnostic tools and effective antiviral regimens have further fuelled the current debate regarding the continuing need to transfuse blood products from CMV-N donors to high-risk patients. Whilst there is some evidence for improved TT-CMV prevention efficacy with selection of seronegative donors, these data have since been superseded by more recent studies affirming the equivalent safety of solely leucodepleted blood products. The safety of such products has been further demonstrated by a modelling approach used by Seed et al that estimated the residual risk of leucodepleted-only products in Australia is negligible (1 in 13 575 000). This risk is very low compared to the risk of acquiring CMV in the community.

In the absence of an international consensus on the optimal strategy to prevent TT-CMV and given the low likelihood of future large scale clinical trials to determine which approach is superior i.e. LR, seroselection or a combination of both, the variation in practices of LR versus combining LR and seroselection is likely to persist. Whilst the latter approach forms the current Australian strategy for preventing TT-CMV, the growing evidence-base supporting the effectiveness of LR alone, as well as improved diagnostic ability to detect TT-CMV and effective antiviral therapy, affirms the necessity for this stance to be reassessed.

Furthermore, the potential for demand for CMV-N components to exceed supply by 2017 if current trends continue, calls into question the future sustainability of this dual approach for managing CMV-safe inventories. Finally, if Australia is to continue managing a separate CMV-N inventory, substantial additional resources will be required to maintain this.

Appendix 3: Comparison of Guidelines on the Clinical Indications for the use of Cytomegalovirus seronegative blood products[5]

Indication	SaBTO[i] 2012	PBM Guidelines[ii] 2015/16	ANZSBT[iii] 2020	NAC Canada[iv] 2017
Intra-uterine transfusions	Yes	Yes	Yes	Yes
Premature neonatal transfusions	Yes	Yes[v]	Yes	No
Other neonatal transfusion (≤ 28 days post EDD)	Yes			
Granulocyte transfusions	Yes	Yes[vi]	Yes	Not specified
Immune deficient patients (Adult)	No	Not specified	No	No
Immune deficient patients (Paediatric)		SCID[vii]		
Autologous HSCT patients	No	No	No	No
Allogeneic HSCT patients (Adults)	No	Not specified	No	No
Allogeneic HSCT patients (Paediatric)		Yes[viii]		
Organ transplant patients	No	No	No	No
Pregnant women	Yes[ix]	Yes	Yes[ix]	No

In 2016 the AABB prepared a committee report on reducing transfusion transmitted CMV rather than develop clinical practice guidelines. [x]

Notes

[i] SaBTO Cytomegalovirus tested Blood Components Position Statement https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215125/dh_133086.pdf

[ii] Patient Blood Management Guidelines Module 5 Obstetrics and Maternity and Patient Blood Management Guidelines Module 6 Neonatal and Paediatrics https://www.blood.gov.au/pbm-guidelines

[iii] Australian and New Zealand Society of Blood Transfusion Guidelines for Transfusion and Immunohaematology Practice- revised 2020 https://www.anzsbt.org.au/data/documents/guidlines/GuidelinesforTransfusionandImmunohaematologyLaboratoryPractice_1ed_Nov20_.pdf

[iv] National Advisory Committee's statement regarding appropriateness of use of Cytomegalovirus (CMV) seronegative vs CMV safe product http://www.nacblood.ca/resources/guidelines/CMV.html

[v] The PBM Guidelines Module 6 Neonatal and Paediatrics – preterm neonates (up to 28 days after expected date of delivery)

[vi] Granulocyte transfusions for CMV negative patients (or unknown status)

[vii] Patient with Severe Combined Immunodeficiency who are CMV negative (paediatric population)

[viii] Stem cell transplants where donor and recipient are CMV negative (paediatric population)

[ix] Pregnant women regardless of CMV status who require regular elective transfusion during pregnancy (not during delivery)

[x] AABB Committee report: reducing transfusion-transmitted cytomegalovirus infections http://dx.doi.org/10.1111/trf.13503[12]

Appendix 4: CMV-seronegative Blood Components Clinical Use Clinical Guidance Summary

Use of CMV-seronegative Blood Components Clinical Guidance Summary

Leucodepletion is standard for all red cell and platelet products released by the Australian Red Cross Blood Service. These standard leucopleted blood components are now considered to be CMV safe and can be used in many situations in which CMV seronegative components would have been used historically.

A recent review by the National Blood Authority* has outlined the remaining indications for use of CMV seronegative components.

CMV seronegative cellular components should continue to be used for the following clinical indications:

- pregnant women regardless of CMV status who require regular elective transfusions during pregnancy (but not during delivery)
- intrauterine transfusion (IUT)
- neonates (up to 28 days post expected date of delivery)
- granulocyte transfusions for CMV negative patients .

In urgent situations, if CMV seronegative blood components are not available then standard leucodepleted (CMV safe) blood components of unknown CMV status should be used to avoid delays.

Standard leucodepleted blood components (CMV safe) can be used in the following situations:

- haemopoietic stem cell transplants (HSCT); all adult and paediatric HSCT patients, for all patient groups including seronegative donor / seronegative recipients
- haematology and oncology patients
- immunodeficient patients, including those with human immunodeficiency virus (HIV)
- solid organ transplants.

Institutions should consider whether to introduce polymerase chain reaction (PCR) monitoring for CMV for at-risk patients to allow early detection of any possible CMV infection.

⚠ Treating / prescribing clinician must ensure the transfusion laboratory & patient / family are aware of need for CMV seronegative blood components; document this in the alert section of medical record and all transfusion requests and relevant prescriptions.

The above indications are taken from the SA Health Clinical Guidance document at inside.sahealth.sa.gov.au/ and as per the tool at http://www.optimalblooduse.eu/app/

* National Blood Authority. Clinical Use of Cytomegalovirus Seronegative Blood Products in Australia. Position Paper. Sep 2017. https://www.blood.gov.au/cytomegalovirus-cmv-seronegative-blood-products

BloodSafe

15. Associated policies / guidelines / clinical guidelines / resources

- SA Health Blood Supply Stewardship Policy Directive
  http://www.sahealth.sa.gov.au/wps/wcm/connect/c68853804d3ef51d96e8ff4c56539eed/Policy_Directive_Blood_Supply_PE+APPROVED.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-c68853804d3ef51d96e8ff4c56539eed-lzo8ZrI

- SA Health. Clinical Services Capability Framework. Maternity and Neonatal Services. August 2016.
  http://www.sahealth.sa.gov.au/wps/wcm/connect/ed65e3804e49ec039092d8c09343dd7f/15137.2-16+Maternity+%26+Neonatal-WebSec.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-ed65e3804e49ec039092d8c09343dd7f-m08cryo

- SA Health South Australian Perinatal Practice Guidelines – Blood Transfusion Clinical Guideline
  http://www.sahealth.sa.gov.au/wps/wcm/connect/401c51004ee1e329ade5add150ce4f37/Blood+transfusion_May2014.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-401c51004ee1e329ade5add150ce4f37-lzo7XVa

- SA Health South Australian Perinatal Practice Guidelines – Massive Blood Transfusion
  https://www.sahealth.sa.gov.au/wps/wcm/connect/401c51004ee1e329ade5add150ce4f37/Blood+Transfusion+and+Massive+Blood+Transfusion+%28perinatal%29_PPG_v7_0.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-401c51004ee1e329ade5add150ce4f37-nJJlBYG

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   http://www.sahealth.sa.gov.au/wps/wcm/connect/c68853804d3ef51d96e8ff4c56539eed/Policy_Directive_Blood_Supply_PE+APPROVED.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-c68853804d3ef51d96e8ff4c56539eed-lzo8ZrI

2. Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products. 12 Nov 2010. https://www.blood.gov.au/stewardship

3. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. Sydney: ACSQHC; 2017.
   https://www.safetyandquality.gov.au/standards/nsqhs-standards

4. SA Health. Clinical Services Capability Framework. Maternity and Neonatal Services. August 2016.
   http://www.sahealth.sa.gov.au/wps/wcm/connect/ed65e3804e49ec039092d8c09343dd7f/15137.2-16+Maternity+%26+Neonatal-WebSec.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-ed65e3804e49ec039092d8c09343dd7f-m08cryo

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   https://www.blood.gov.au/cytomegalovirus-cmv-seronegative-blood-products

6. Seed CR, Wong J, Polizzotto MN, Faddy H, Keller AJ, Pink J. The residual risk of transfusion-transmitted cytomegalovirus infection associated with leucodepleted blood components. Vox sanguinis. 2015;109(1):11-7.

7. Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). Report of the Cytomegalovirus Steering Group. Mar 2012.
   https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215126/dh_132966.pdf

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Cytomegalovirus tested blood components: Position statement. Mar 2012. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215125/dh_133086.pdf

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14. National Advisory Committee's statement regarding appropriateness of use of Cytomegalovirus (CMV) sero negative vs CMV safe product. Canada. 2017. https://www.nacblood.ca/resources/guidelines/CMV.html

15. Australian and New Zealand Society of Blood Transfusion (ANZSBT) Ltd. Australian College of Nursing. Guidelines for the Administration of Blood Products. 3rd Edition. revised 2019. ANZSBT. https://anzsbt.org.au/wp-content/uploads/2020/03/ANZSBT-Administration-Guidelines-Revised-3rd-edition-Publication-Version-FINAL-20191002.pdf

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17. Document Ownership and History

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