

Irradiated Blood Components for Clinical Use Clinical Guidance

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Irradiated Blood Components for Clinical Use

Clinical Guidance

1. Summary of Indications for Clinical Use of Irradiated Products

This Clinical Guidance sets out the patient groups for whom transfusion with irradiated blood components is clinically indicated, based on the British Committee for Standards in Haematology Guidelines (2010)¹ and supported by a 'Special Blood Components' tool² to assist implementation. Section 7 provides detailed recommendations.

Summary of indications for use of irradiated blood components (See Appendix 2):

- Alemtuzumab (MabCampath[®], Lemtrada[®])
 - should be used after alemtuzumab (anti-CD52) therapy
 - review as new potent immunosuppressive drugs and biologicals are introduced
- Allogeneic haemopoietic stem cell transplant
 - from time of initiation of conditioning chemoradiotherapy
 - continue while patient receives graft-versus-host disease prophylaxis
 - allogeneic blood transfused to donors 7 days prior to or during harvest
- Autologous bone marrow or stem cell harvest and transplant
 - during and for 7 days before bone marrow / stem cell harvest
 - from initiation of conditioning chemo / radiotherapy until 3 months post-transplant (6 months if total body irradiation was used)
- Blood from a relative
 - all transfusions from first- or second-degree relatives
- Granulocytes for recipients of any age
- Hodgkin lymphoma for all ages, at any stage of the disease, for life
- Human Leucocyte Antigen (HLA)-selected / matched components
 - all components even if the patient is immunocompetent
- Intrauterine transfusions (IUT) and all subsequent top up blood transfusions
 - Intrauterine and all subsequent transfusions post-delivery until 6 months after expected date of delivery (40 weeks gestation)
- Neonatal alloimmune thrombocytopenia (NAIT)
 - IUT of platelets and any subsequent red cell or platelets until 6 months after expected date of delivery (40 weeks gestation)
- Neonatal exchange transfusions (ET)
 - previous IUT or donation from a first- or second-degree relative
 - other ET cases provided this doesn't unduly delay transfusion
- Purine analogue drugs and new and related agents
 - indefinitely for patients treated with purine analogue drugs (fludarabine, cladribine, and deoxycoformicin/pentostatin)
 - other purine antagonists and new and related agents, e.g. bendamustine and clofarabine - recommended due to similar mode of action
- All severe T lymphocyte immunodeficiency syndromes (diagnosed or suspected)
 - start as soon as diagnosis suspected, in uncertainty, consult clinical immunologist
 - high index of suspicion is required in infants and children with cardiac anomalies, dysmorphic features, craniofacial abnormalities, hypocalcaemia and lymphopenia

(NB. All platelets provided by the Australian Red Cross Blood Service are irradiated before release)

Irradiated blood components are NOT required for:

- Infant top up transfusions unless for the above indications
- Adults or children with acute leukaemia, except for HLA-selected / matched components or any of the other indications listed above.

Contraindications:

Irradiation is contraindicated for hematopoietic progenitor cell and donor lymphocyte infusions as it will inhibit their ability to engraft and achieve their desired effects.⁴

Emergency transfusion:

If irradiated components are not available, in the event of an emergency, patients must be supported with standard components.⁸

Communication of the requirement for irradiated products:

Mechanisms must be in place for appropriate and timely communication of information. Robust systems for communicating and documenting patients' special requirements should be developed and implemented (including empowering patients).

- Any special blood product requirements must be communicated to the transfusion service provider by the prescribing clinician as soon as they become known, so that a record can be made in the laboratory information system.¹⁰
- The clinician requesting the crossmatch or blood product is responsible for ensuring irradiated components are requested for appropriate patients. It is the clinician's responsibility to ensure that accurate clinical information appears on the request form.¹¹
- The special requirements must also be documented on the prescription each time the product is prescribed and the blood product checking procedure must ensure the blood product is checked for compliance with any special requirements on the prescription.¹⁰
- Clear communication channels should be developed with the local transfusion laboratory, pharmacy, shared-care hospitals to further minimise the risk of TA-GvHD to patients.⁹

2. Introduction

The SA Health Blood Supply Stewardship Policy Directive³ requires all SA Health services to implement programs, strategies, policies and guidelines that contribute to the safe, responsible and appropriate use of blood and blood products. The Directive is based on the Australian Health Ministers' Conference Statement on National Stewardship Expectations for the Supply of Blood and Blood Products⁴. Health providers should ensure all blood products are used in a clinically appropriate manner in accord with relevant professional guidelines and standards.

In addition, the National Safety and Quality Health Service Standard 7 - Blood Management⁵ states Health Service organisations should implement policies and procedures for blood management that address prescribing practice and the appropriate

and safe clinical use of blood and blood products. This Standard also has education and training requirements.

There are significant logistics (and associated costs) in the provision of the limited supply of irradiated 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 Clinical Guidance to ensure optimal clinical use of irradiated products in South Australia.

3. Background

Irradiated blood components are used to prevent Transfusion-associated graft-versus host disease (TA-GvHD), the primary cause of which is proliferation and engraftment of transfused donor T-lymphocytes in the bone marrow of susceptible recipients.

All blood components containing viable lymphocytes potentially can cause TA-GvHD. Whole blood, red cells, platelets and granulocytes have been implicated as causes of TA-GvHD. Frozen components and fractionated components have not been implicated in TA-GvHD.⁶

TA-GvHD is a rare, but almost universally fatal, iatrogenic complication of transfusion. The inherent risk associated with an individual transfusion depends on the interplay of several factors, including the number and viability of contaminating lymphocytes in the transfused cellular component, the susceptibility of the patient's immune system to the engraftment of donor lymphocytes, and the degree of immunological (human leucocyte antigen, HLA) homology between the donor and the recipient⁴. Gamma irradiation to inactivate viable T lymphocytes contained within the blood components remains the mainstay in prevention of TA-GvHD; x-ray irradiation has also been shown to provide an equivalent effect.⁶

4. Definitions / Acronyms

HLA	human leucocyte antigen
NSQHS	National Safety and Quality Health Service
TA-GvHD	Transfusion-associated graft-versus-host disease

5. Principles of the standards

The South Australian Blood Management Council supports the use of the British Committee for Standards in Haematology (BCSH) Guidelines on the use of irradiated blood components (2010)⁴ which have been reproduced within this document (see section 6). These guidelines are based on a systematic review of the literature to June 2009 and have graded recommendations with clear indications and an 'app' facilitating implementation. They include all 'definite' indications in current Australian guidelines as outlined below:

The Australian and New Zealand Society of Blood Transfusion (ANZSBT) Guidelines (2011)⁶ were based on the BCSH guidelines (2010)⁴ along with an updated literature review and guidelines from other bodies. Recommendations are listed as 'definite' (strong evidence or clear consensus), 'possible' (case reports, no controlled studies available), 'no indication' (no cases or insufficient evidence).

The Australian Patient Blood Management (PBM) Guidelines: Module 6 - Neonatal and Paediatrics (2016)⁷ include expert opinion points relating to irradiation with indications based on the ANZSBT Guidelines (2011)⁶ ('absolute' and 'relative' indications are outlined). These are reproduced in Appendix 1. While all 'absolute' indications are covered in the BCSH (2010)¹ guidelines, a notable difference in the paediatric setting relates to small volume transfusions in neonates (where there hasn't been a preceding IUT). The BCSH guidelines (2010)⁴ advise that transfusion of irradiated red cells for small-volume transfusion is not necessary in this setting. The Australian Neonatal and Paediatric PBM guidelines (2016)⁷, which are consistent with the ANZSBT guidelines (2011)⁶, advise that transfusion of irradiated products 'may be considered' in neonates of birth weight of ≤ 1300 grams ('relative' indication).

6. General

This Guidance may not be appropriate in all patient situations, and individual circumstances may dictate an alternative approach.

Expiry⁶:

- Red cells may be irradiated at any time up to 14 days after collection, and thereafter stored for a further 14 days from the date of irradiation.
- For IUT, exchange transfusion and neonatal indications, transfuse red cells within 24 hours of irradiation, and by 5 days or less from collection.
- Platelets can be irradiated at any stage in their shelf-life and thereafter stored up to their normal 5 day expiry. All platelets provided by the Australian Red Cross Blood Service are irradiated before release.
- Granulocytes should be irradiated as soon as possible after manufacture / collection, and thereafter transfused with minimal delay.

Side effects and hazards of irradiation:

Irradiation of red cells causes an increase in the level of extracellular potassium. The clinical significance of the potassium load depends on the speed and volume of the transfusion, as well as the age of the blood.⁶

The Australian PBM Guidelines: Module 6 - Neonatal and Paediatrics (2016)⁷ caution that hyperkalaemia may occur when large volumes of irradiated blood are transfused and advise that in patients at risk, irradiated blood should be as fresh as possible (<7 days) and used within 24 hours of irradiation (expert opinion point for neonates and paediatric patients)⁷.

7. Key recommendations regarding clinical indications

(As extracted from BCSH Guidelines on the use of irradiated blood components¹). Levels and grades of evidence used are in brackets.

NB. All platelets provided by the Australian Red Cross Blood Service are irradiated before release.

1. General

- 1.1. Donations from first or second degree family members (Grade 1 recommendation; level B evidence).
- 1.2. All HLA-selected / matched products (Grade 2 recommendation; level C evidence).
- 1.3. All granulocytes (Grade 1 recommendation; level C evidence).

2. Paediatric practice

- 2.1. *Intrauterine and exchange transfusions (IUT and ET) (Grade 1 recommendation; level B evidence).*
- *Blood for neonatal ET must be irradiated if there has been a previous IUT or if the donation comes from a first- or second-degree relative. (Grade 1 recommendation; level B evidence).*
 - *For other neonatal ET cases, irradiation is recommended provided this does not unduly delay transfusion. (Grade 1 recommendation; level C evidence).*
- 2.2. *Top-up red cell transfusions in term and pre-term infants in specific circumstances*
- *For a previous IUT, irradiated components should be administered until 6 months after the expected delivery date (40 weeks gestation). (Grade 2 recommendation; level C evidence).*
 - *Where the donation has come from a first- or second-degree relative. (Grade 2 recommendation; level C evidence).*
- 2.3. *Platelet transfusions in the fetus and infant*
- *Platelets transfused in utero should be irradiated and any subsequent red cell or platelet transfusions irradiated until 6 months after the expected date of delivery (40 weeks gestation). (Grade 1 recommendation; level C evidence).*
 - *Platelets donated by first- or second-degree relatives. (Grade 1 recommendation; level C evidence).*
- 2.4. *Congenital immunodeficiency in infants and children*
- *All severe T lymphocyte immunodeficiency syndromes. (Grade 1 recommendation; level A evidence).*
 - *Once a diagnosis of immunodeficiency has been suspected, irradiated components should be given while further diagnostic tests are being undertaken. A clinical immunologist should be consulted for advice in cases where there is uncertainty. (Grade 1 recommendation; level A evidence).*
- 3. *Allogeneic bone marrow or peripheral blood stem cell transplantation***
- *All recipients of allogeneic haemopoietic stem cell transplantation (HSCT) must receive irradiated blood components from the time of initiation of conditioning chemoradiotherapy. (Grade 1 recommendation; level B evidence).*
 - *Irradiated components should be continued while the patient continues to receive GvHD prophylaxis, i.e. usually for 6 months post-transplant, or until the lymphocyte count is $>1 \times 10^9/L$. If chronic GvHD is present or if continued immunosuppressive treatment is required, irradiated blood components should be given indefinitely. (Grade 2 recommendation; level C evidence).*
 - *Allogeneic blood transfused to bone marrow and peripheral blood stem cell donors 7 days prior to or during the harvest should also be irradiated. (Grade 1 recommendation; level C evidence).*
- 4. *Autologous bone marrow or peripheral blood haemopoietic stem cell transplantation***
- *Patients undergoing bone marrow or peripheral blood stem cell 'harvesting' for future autologous re-infusion should receive irradiated cellular blood components during and for 7 days before the bone marrow / stem cell harvest to prevent the collection of viable allogeneic T lymphocytes, which can potentially withstand cryopreservation. (Grade 2 recommendation; level C evidence).*
 - *All patients undergoing autologous bone marrow transplant or peripheral blood stem cell transplant should receive irradiated cellular blood components from initiation of conditioning chemo/radiotherapy until 3 months post-transplant (6*

months if total body irradiation was used in conditioning). (Grade 2 recommendation; level C evidence).

5. Other patient groups

5.1. Lymphoma

- All adults and children with Hodgkin lymphoma at any stage of the disease should have irradiated red cells and platelets for life. (Grade 1 recommendation; level B evidence).

5.2. Purine analogue and new and related drugs

- Patients treated with purine analogue drugs (fludarabine, cladribine and deoxycoformicin / pentostatin) should receive irradiated blood components indefinitely. (Grade 1 recommendation; level B evidence).
 - The situation with other purine antagonists and new or related agents, such as bendamustine and clofarabine, is unclear, but use of irradiated blood components is recommended as these agents have a similar mode of action.
 - Irradiated blood components should be used after alemtuzumab (anti-CD52) therapy.
 - Use of irradiated red cells and platelets after rituximab (anti-CD20) is not recommended at this time. (Grade 2 recommendation; level C evidence).
- As new potent immunosuppressive drugs and biological agents are introduced into practice there is a need for regular review of these recommendations. (Grade 2 recommendation; level C evidence).

5.3. Aplastic anaemia

- In view of the recent switch from horse anti-thymocyte globulin (ATG) to the more immunosuppressive rabbit ATG, we now recommend use of irradiated blood components for aplastic anaemia patients receiving immunosuppressive therapy with ATG (and / or alemtuzumab). (Grade 2 recommendation; level C evidence).
- It is currently unclear as to how long irradiated components should continue to be used after ATG administration.

6. Patient groups where irradiated blood products are not necessary

6.1. Top-up red cell transfusions in term and pre-term infants in specific circumstances

- It is not necessary to irradiate red cells for routine 'top-up' transfusions of premature or term infants unless either there has been a previous IUT, in which case irradiated components should be administered until 6 months after the expected delivery date (40 weeks gestation), or the donation has come from a first- or second-degree relative. (Grade 2 recommendation; level C evidence) (See 2.2).

6.2. Platelet transfusions in the fetus and infant

- There is no need to irradiate other platelets transfusions for pre-term or term infants **except** as indicated above.

6.3. Acquired immunodeficiency states

- There is currently no indication for irradiation of cellular blood components for infants or children who are suffering from a common viral infection, who are HIV antibody positive, or who have AIDS. (Grade 2 recommendation; level B evidence).
- There is also no indication for irradiation of cellular blood components for adults who are HIV antibody positive or who have AIDS. (Grade 2 recommendation; level B evidence).

6.4. Cardiac surgery in neonates and infants

- There is no need to irradiate red cells or platelets for infants undergoing cardiac surgery unless clinical or laboratory features suggest a coexisting T lymphocyte immunodeficiency syndrome. (Grade 2 recommendation; level B evidence).

6.5. Acute leukaemia

- It is not necessary to irradiate red cells or platelets for adults or children with acute leukaemia, except for HLA-selected / matched products or donations from first- or second-degree relatives. (Grade 1 recommendation; level B evidence). See 5.2 for treatment with purine analogue drugs.

6.6. Routine surgery, solid tumours, organ transplantation, auto immune disorders and acquired immunodeficiency









- It is not necessary to irradiate blood components for patients undergoing routine surgery, those with solid tumours, HIV infection, autoimmune diseases or after solid organ transplantation (unless alemtuzumab (anti-CD52) has been used in the conditioning regimen), or there is another indication (eg. the patient is receiving HLA selected / matched products). The effects of new regimens of chemo- and immunotherapy entering clinical practice must continue to be monitored. (Grade 2 recommendation; level C evidence).

8. Workforce implications

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

9. 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
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Recommendation

- All incidents, including cases of TA-GvHD, should be reported via SLS. This includes 'near misses', such as when a non-irradiated component is transfused to a patient where irradiated products were indicated but no harm occurred.
- Patients at risk of TA-GvHD should be made aware of their need for irradiated blood components by the prescribing clinician and be provided with appropriate written information.
- The BCSH (2010)¹ endorses the recommendations from SHOT (<http://www.shotuk.org>) relating to improved clinical and laboratory awareness, documentation and communication of special requirements for transfusion, including irradiated components.
- Initiatives to improve laboratory and clinical information management systems (including IT links with Pharmacy and diagnostic services to highlight 'at risk' patients) should be incorporated into local policies and regularly audited.
- Poor communication between centres involved in 'shared care' of patients is a well-reported hazard.¹
- Health Service organisations should undertake audits or compliance reviews to ensure this Guidance is implemented and laboratories should also consider auditing their requests for irradiated blood components to monitor compliance.

10. Eligibility criteria

Inclusion

All SA Health clinical and laboratory staff involved in the supply, prescription and administration to patients requiring irradiated blood components.

11. Appendices

Appendix 1 Australian PBM Guidelines Module 6 Neonatal and Paediatrics

Table 1 Indications for irradiation of cellular products		
	Absolute Indications (RBCs, Platelets and Granulocytes must be Irradiated)	Relative indications (irradiation of cellular products may be considered)
Fetus and neonate	<ul style="list-style-type: none"> ▪ IUT ▪ IUT and subsequent transfusions up to the age of 6 months 	<ul style="list-style-type: none"> ▪ Neonatal exchange transfusion (provided no critical delay in transfusion) ▪ Neonates with a birth weight of ≤1300 g (especially if gestation <28 weeks or birth weight <900 g)
Immunodeficiency	<ul style="list-style-type: none"> ▪ Known or suspected congenital cellular immunodeficiency (e.g. SCID, Wiskott Aldrich syndrome, ataxia telangiectasia and 22q11 deletion syndromes) 	
Specific blood products	<ul style="list-style-type: none"> ▪ HLA-matched cellular products other than stem cells ▪ Blood components donated by first or second-degree relatives 	
Stem cell transplantation	<ul style="list-style-type: none"> ▪ Allogeneic and autologous transplantation 	<ul style="list-style-type: none"> ▪ See relevant guidelines for advice on when use of irradiated products can cease
Chemotherapy and malignancy	<ul style="list-style-type: none"> ▪ Hodgkin lymphoma – indefinitely ▪ Treatment with purine analogues – indefinitely ▪ Treatment with Alemtuzumab (anti-CD52) therapy – at least 12 months from last dose ▪ Treatment with ATG – recommendations for duration are not available, consider indefinitely 	<ul style="list-style-type: none"> ▪ All other patients undergoing chemotherapy should be decided on an individual basis, taking into account the intensity of the immunosuppression

ATG, antithymocyte globulin; HLA, human leucocyte antigen; IUT, intrauterine transfusion; RBC, red blood cell; SCID, severe combined immunodeficiency

Table 2 Expert Opinion Points

Irradiated Cellular Blood Products	
EOP10	<p>Irradiated cellular blood products (RBCs and platelets) are used to prevent transfusion-associated graft-versus-host disease, and are indicated for:</p> <ul style="list-style-type: none"> ▪ intrauterine transfusion, and recipients of prior intrauterine transfusion up to 6 months of age ▪ suspected or known severe congenital T-cell immunodeficiency (e.g. severe combined immunodeficiency) ▪ severe acquired T-cell dysfunction, related to either disease or drug therapy (see published guidelines^{4,6}) ▪ human leukocyte antigen-matched cellular blood products (RBCs, platelets and granulocytes). <p>They may also be considered for:</p> <ul style="list-style-type: none"> ▪ neonatal exchange transfusion, provided this does not unduly delay transfusion ▪ very low birth weight neonates, especially extremely preterm (<28 weeks) or extremely low birth weight infants <p>certain patients undergoing chemotherapy (depending on degree of immunosuppression).</p>
EOP11	Stem cells must not be irradiated.
EOP12	Hyperkalaemia may occur when large volumes of irradiated blood are transfused. In patients at risk, irradiated blood should be as fresh as possible (<7 days) and used within 24 hours of irradiation.
EOP13	Patients at high risk of transfusion-associated graft-versus-host disease should be informed of the need for irradiated blood products. Also, alerts should be incorporated in the information systems of the health service and transfusion laboratory.
'Fresh' RBCs in fetal, neonatal and paediatric patients	
EOP7	<p>'Fresh' (<7 days) RBCs are not advocated for routine use, but may be considered in the following clinical situations:</p> <ul style="list-style-type: none"> ▪ intrauterine transfusion (<5 days, if available) ▪ large-volume transfusion (>25 mL/kg) ▪ exchange transfusion ▪ cardiac surgery ▪ transfusion-dependent chronic anaemia (RBCs <14 days) ▪ where irradiated blood products are used.

EOP, expert opinion point; RBC, red blood cell

Clinical Guidance on Use of Irradiated Blood Components

All blood components containing viable lymphocytes can potentially cause fatal Transfusion-Associated Graft-versus-Host-Disease (TA-GvHD). Irradiation is therefore relevant for red cells, platelets, whole blood & granulocytes.

Indications for irradiated blood components (if in doubt seek expert advice)

Always check for currency as new therapies are introduced

Allogeneic haemopoietic stem cell transplant and harvest

- from commencement of conditioning chemoradiotherapy
- continue while patient receives graft-versus-host disease prophylaxis
- allogeneic blood transfused to stem cell donors 7 days prior to or during harvest

Autologous bone marrow or stem cell harvest and transplant

- during and for 7 days before bone marrow / stem cell harvest
- from initiation of conditioning chemo / radiotherapy until 3 months post-transplant (6 months if total body irradiation was used)

Hodgkin lymphoma for all ages, at any stage of the disease, for life

All severe T lymphocyte immunodeficiency syndromes (diagnosed or suspected)

- start as soon as diagnosis suspected, in uncertainty, consult clinical immunologist
- high index of suspicion is required in infants and children with cardiac anomalies, dysmorphic features, craniofacial abnormalities, hypocalcaemia and lymphopenia

Patients receiving specific agents:

Purine analogue drugs (fludarabine, cladribine, and deoxycytosine / pentostatin) and new and related agents (e.g. bendamustine and clofarabine) – all protocols

- indefinitely for treated patients

Alemtuzumab (MabCampath[®], Lemtrada[®]) (anti-CD52) plus others

- review as new potent immunosuppressive drugs and biologicals are introduced

Specific types of blood products:

Human Leucocyte Antigen (HLA)-selected / matched components

- all components even if patient is immunocompetent

Transfusions from 1st- or 2nd-degree relatives

- all components even if patient is immunocompetent

Granulocytes for recipients of any age

Intrauterine and subsequent transfusions; neonatal exchange transfusion:

Intrauterine transfusions (IUT)

- including all subsequent transfusions post-delivery until 6 months after expected date of delivery (40 weeks gestation)

Neonatal exchange transfusions (ET)

- previous IUT or donation from a 1st- or 2nd-degree relative
- other ET cases provided this does not unduly delay transfusion

Neonatal alloimmune thrombocytopenia (NAIT)

- IUT of platelets and any subsequent transfusion of red cells or platelets until 6 months after expected date of delivery (40 weeks gestation)

⚠ Treating / prescribing clinician must ensure the transfusion laboratory and patient / family are aware of need for irradiated 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 contained in the tool at <http://www.optimalblooduse.eu/app/>

Reasonable care has been taken to ensure this information is up to date & accurate at the time of creation. SA Health does not warrant its completeness and excludes liability where permitted by law. Health care professionals must continue to rely upon their own skill, care and inquiries taking into account the individual circumstances of each patient when providing medical advice.

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BloodSafe

12. Associated Directives / Guidelines

SA Policy Directives

1. 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-lzo8Zrl
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14. Document Ownership & History

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