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EXTENDED LIFE PLASMA: A FRAMEWORK FOR PREPARATION, STORAGE AND USE

Australian & New Zealand
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Foreword

ANZSBT Council is pleased to publish the second edition of the guidelines document *Extended Life Plasma: A Framework for Preparation, Storage and Use* (formerly *Thawed Plasma Components: A Framework for Preparation, Storage and Use)*.

These guidelines were developed by the ANZSBT Transfusion Science Standing Committee and supersede the previous edition from April 2009. As you will note, this edition represents not only revision of the guidelines but also a name change which more accurately reflects the scope of the document.

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Glossary

°C	Degrees Celsius
ACHS	Australian Council on Healthcare Standards
ACSQHC	Australian Commission on Safety and Quality in Health Care
ANZSBT	Australian and New Zealand Society of Blood Transfusion
aPTT	Activated partial thromboplastin time
AS	Australian Standard
ASBT	Australasian Society of Blood Transfusion
ASTH	Australasian Society of Thrombosis and Haemostasis
Blood component	Red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate, cryosupernatant, whole blood or granulocytes
Blood Service	National supplier of blood components (Australian Red Cross Blood Service or New Zealand Blood Service [NZBS] unless otherwise indicated)
Controlled storage	Equipment, including transport containers, validated for storage of blood components Validation should include specific policies and procedures describing packing conditions, length of time blood components may be held in storage, maintenance and temperature monitoring
DEHP	Di(2-ethylhexyl) phthalate is a commonly used plasticiser (or softener) added to plastics such as PVC to make them flexible
DIC	Disseminated intravascular coagulation
Extended Life Plasma (ELP)	FFP which has been thawed but not subsequently allocated to a specific patient and intended for extended storage (at 2-6°C) beyond 24 hours and up to a maximum of 5 days from the day of thawing ELP has similar physical properties to FFP although the levels of factors V, VII and VIII are reduced
Fresh Frozen Plasma (FFP)	Plasma frozen within 18 hours of collection and stored at or below -25°C for up to one year FFP contains all known coagulation and anticoagulant proteins in concentrations similar to those found in normal individuals and once thawed has a shelf-life of 24 hours (when stored at 2-6°C)

Glossary *continued*

Health service	An institution or group of institutions where healthcare is provided; transfusion of blood components may occur across a range of settings including hospitals and day treatment centres
HELLP syndrome	A group of symptoms that occur in pregnant women who have: **H** - haemolysis, **EL** - elevated liver enzymes and **LP** - low platelet counts and may be seen in association with pre-eclampsia or eclampsia
Hospital transfusion service	The hospital pathology laboratory or private pathology provider supplying transfusion services e.g. pretransfusion testing and/or provision of blood components to a hospital (or network of hospitals) or other health services
HTC	Hospital Transfusion Committee
HUS	Haemolytic uremic syndrome; a disorder that usually occurs when an infection in the digestive system produces toxins that destroy red cells, causing kidney injury HUS often occurs after a gastrointestinal infection with E. coli (O157:H7) but has also been linked to other gastrointestinal infections, including shigella and salmonella, as well as non-gastrointestinal infections
INR	International normalised ratio
IANZ	International Accreditation New Zealand
Labelling	Steps taken to identify the original plasma donation, any components produced from it and any modifications; the attachment of appropriate labels to a component
NATA	National Association of Testing Authorities (Australia)
NBA	National Blood Authority (Australia)
NHMRC	National Health and Medical Research Council (Australia)
NPAAC	National Pathology Accreditation Advisory Council (Australia)
PCC	Prothrombin complex concentrate; a freeze-dried plasma product formulated with three factors (II, IX and X) or four factors (II, VII, IX and X); Prothrombinex-VF is the only product currently used in Australia and NZ
PT	Prothrombin time
RCPA	Royal College of Pathologists of Australasia

Glossary *continued*

Request	The mechanism for communicating with the transfusion laboratory, asking them to prepare and issue a blood component for administration
SOP	Standard operating procedure
TACO	Transfusion-associated circulatory overload
TGA	Therapeutic Goods Administration (Australia)
Thawed plasma components	Refers to thawed FFP or ELP
TRALI	Transfusion-related acute lung injury
TTP	Thrombotic thrombocytopenic purpura

Introduction

A variety of fresh plasma components are available and these are generally stored frozen until required for transfusion. All plasma components contain coagulation factors, but in differing relative amounts. With rare exceptions, they are used to treat patients with coagulopathy who are bleeding or are at risk of bleeding and where treatment with vitamin K or specific factor concentrates is not appropriate or is unavailable.

The aim of these guidelines is to provide a framework for the preparation, storage and use of ***extended life plasma*** (ELP) a complementary component to thawed fresh frozen plasma (FFP).

Rapid provision of FFP in emergency situations is restricted by the time taken to thaw and release the plasma unit(s). On the other hand ELP, which is stored in the liquid state (at 2-6°C) for up to 5 days after thawing, allows a hospital transfusion service to have thawed plasma readily available which can then be provided with minimal delay in time-critical clinical or emergency situations. Another benefit of using ELP is a potential reduction in wastage of thawed plasma because of a greater likelihood it will be used during the extended shelf-life.

The decision to keep an inventory of ELP should be made after due consideration of the pros and cons for its use in the local setting. It should be noted that ELP may not be suitable for all patient groups or situations e.g. it is not recommended for neonatal transfusion (see 1.3) and FFP should continue to be used in this context.

A hospital transfusion service may decide to only maintain an inventory of ELP rather than a dual inventory of FFP and ELP depending on clinical requirements. Where a hospital transfusion service supports a hospital (or health service) having only small numbers of trauma or emergency cases the holding of an inventory of ELP is not recommended.

Key points

(i) These guidelines outline the minimum requirements for introducing and managing an inventory of ELP.

(ii) The activities associated with ELP are an extension of those that will be in place if already managing an inventory of frozen components, the assessment of which by NATA/RCPA (or IANZ in New Zealand) is part of a hospital transfusion service's routine laboratory accreditation.

(iii) Although not specifically required by these guidelines the hospital transfusion service may elect to perform sterility testing and/or measure coagulation factor levels on expired units of ELP to validate their processes.

(iv) The procedural framework described in the guidelines has been endorsed by ANZSBT, NATA/RCPA, the Australian Red Cross Blood Service and TGA. This relates to the process only. Individual hospitals retain responsibility for its application and any recommendations.

Section 1
Properties Of Extended Life Plasma

1.1 Coagulation factor levels

ELP has similar physical properties to FFP although there are reduced levels of factors V, VII and VIII (see table 1). Research shows that the labile coagulation factor levels remain at haemostatic levels for up to 5 days following thawing.

Table 1: Comparison of coagulation factors levels (IU/mL) in FFP at thawing and after extended post thaw storage at 2-6°C

Factor	**FFP (at thawing)** (n=30 FFP; n=30 cryodepleted plasma)	**Day 3** (post thaw)	**Day 5** (post thaw)
Factor V	0.89 ± 0.14	0.83 ± 0.17	0.75 ± 0.13
Factor VII	1.0 ± 0.21	0.89 ± 0.17	0.85 ± 0.17
Factor VIII	1.08 ± 0.33	0.63 ± 0.18	0.56 ± 0.15

(*Australian Red Cross Blood Service data used with permission*)

1.2 Microbiological sterility

The sterility of thawed plasma (stored for 5 days at 2-6°C) was demonstrated in preliminary microbiological validation testing performed by the Australian Red Cross Blood Service, the results of which are shown in table 2 below:

Table 2: Microbiological testing data for thawed plasma

Test performed (n=107)	**Result**
7 day aerobic culture following thawing and storage at 2-6°C	No growth
7 day anaerobic culture following thawing and storage at 2-6°C	No growth

(*Australian Red Cross Blood Service data - used with permission*)

1.3 Di(2-ethylhexyl)phthalate (DEHP)

DEHP is one of a family of chemicals known as plasticisers which are commonly added to plastics as a softener to make them flexible. The DEHP in plastic blood bags has been shown to leach into the protein and lipid rich contents of the bag during storage.

DEHP is reported to cause a variety of adverse effects in experimental animals most notably reproductive toxicity in rats. Whilst this toxicity is well established in animal models the potential effects on humans remain controversial.

In the context of these guidelines the consequences of transient exposure to DEHP from plasma transfusions are similarly unclear. Despite concerns over toxicity in animals it is thought highly unlikely that DEHP will cause any harm to adult transfusion recipients. This is also likely to be true for neonatal recipients but should clinicians wish to keep DEHP exposure to a minimum in this vulnerable patient group it would be prudent to use FFP thawed and refrigerated for less than 24 hours (Transfusion 2012; 52: 493-502).

Section 2
Clinical Use Of Plasma Components

In most clinical situations randomised controlled trials provide little or no evidence to support using FFP with the reported benefits often overstated in both the prophylactic and therapeutic settings.

Transfusion of plasma components should only be prescribed for appropriate indications in accordance with relevant clinical guidelines and following the principles of evidence-based patient blood management (PBM).

New national *Patient Blood Management Guidelines* supersede previous the NHMRC/ASBT *Clinical Practice Guidelines* (2001). The new PBM guidelines represent collaboration between the National Health and Medical Research Council (NHMRC), ANZSBT, NBA and specialist colleges and societies.

Because there are no published guidelines specifically describing the use of ELP this section therefore provides a description of the clinical use of plasma components in the broader sense.

2.1 Fresh Frozen Plasma (FFP)

A single unit of FFP usually contains around 280 - 300 mL of plasma. FFP provides all known coagulation and anticoagulant proteins in concentrations similar to those found in normal individuals.

FFP may be transfused in a range of clinical situations including both congenital and acquired deficiencies of the stable clotting factors (II, VII, IX, X, XI, and XIII) where other therapies or specific factor concentrates are unavailable or inappropriate. Adequacy of replacement may be monitored by the relevant coagulation studies. The decision to transfuse FFP for the following indications should be based on the relevant clinical guidelines and expert guidance sought where necessary:

- Non-bleeding patients who are undergoing invasive procedures and who are considered at significant risk for bleeding in association with prolonged coagulation test results generally PT and/or aPTT greater than 1.5 times the mean of the reference range.
- Treatment or prevention of bleeding in patients with known hereditary coagulation abnormalities where no specific factor concentrate is available. Plasma may also be appropriate for non-bleeding patients with a personal or family history of bleeding during invasive procedures.
- Urgent reversal of warfarin to stop bleeding or prior to emergency surgery in a non-bleeding patient used in conjunction with vitamin K and/or prothrombin complex concentrate (PCC; e.g. Prothrombinex-VF) [see: *An update of consensus guidelines for warfarin reversal;* MJA 198(4) 4 March 2013].
- Bleeding due to multiple coagulation factor deficiencies. Such patients may include those with liver disease, DIC, trauma, massive transfusion, cardiac bypass surgery, microvascular bleeding with prolonged PT, INR or aPTT, or other medical conditions.
- Thrombotic thrombocytopenic purpura (TTP) or other thrombotic microangiopathy (e.g. HUS or HELLP syndrome).
- Rare indications:
  - (i) factor XIII deficiency, as an alternative to cryoprecipitate
  - (ii) prophylactic or therapeutic replacement of anticoagulant proteins (e.g. antithrombin III, protein C, protein S) whenever specific concentrates are not available
  - (iii) C1-esterase inhibitor deficiency (life-threatening hereditary angioedema)

2.2 Extended Life Plasma (ELP)

Although there are no published guidelines specifically describing its clinical use, ELP has similar characteristics and therefore clinical utility to FFP and in most cases can be considered a complementary component.

It should however be noted that ELP is not recommended for use in patients with congenital factor V or VIII deficiencies, if specific factor concentrates are available or if an alternate specific therapy is available. Use of ELP should also be avoided in neonatal patients (see 1.3).

ELP allows a hospital transfusion service to have thawed plasma readily available which can then be provided with minimal delay in time-critical clinical or emergency situations. Another benefit of using ELP is a potential reduction in wastage of thawed plasma because of a greater likelihood it will be used during the extended shelf-life.

2.3 Requests for thawed plasma components

Requests for thawed plasma components should be managed on a case-by-case basis in accordance with relevant clinical polices and guidelines.

2.4 Administration of plasma components

Transfusion of thawed plasma components should be started as soon as possible after issue from the Blood Bank (or removal from an approved blood refrigerator or validated transport container).

The transfusion should be completed promptly, within the clinical constraints of the patient's clinical status and in accordance with hospital blood component administration policies and/or the ANZBST *Guidelines for the administration of blood products.*

2.5 Adverse transfusion reactions and other adverse events

The major potential transfusion-related risks are equally applicable to ELP as other types of plasma component and include:

a) transfusion-related adverse reactions e.g. non-haemolytic febrile transfusion reactions (NHFTR), allergic type reactions, TRALI and TACO

b) contamination of the component from bacteria introduced during handling, storage or thawing

c) proliferation of bacterial contamination, which may have occurred at any stage of manufacturing, handling, storage or thawing, during post-thaw storage

d) inappropriate or unnecessary plasma transfusion

e) compromised coagulation factor activity due to inappropriate storage conditions (temperature fluctuations, inadequate temperatures)

Each health service shall have a system for detecting, evaluating, documenting and reporting suspected transfusion reactions or other adverse events associated with transfusion of plasma components.

Adverse reactions or events should be reported to the hospital transfusion service and if required to the local haemovigilance programme and Blood Service. Confirmed cases of infectious diseases attributable to the transfusion of plasma components shall also be notified to the relevant authorities in accordance with applicable state or territory and national regulations and statutory requirements.

2.6 Management of thawed plasma components

2.6.1 Conversion of thawed FFP to ELP

FFP not transfused within 24 hours of thawing may be converted to ELP as long as it has been maintained under appropriately controlled storage.

2.6.2 Accepting unused thawed plasma components for return to inventory

If transfusion cannot be started within 30 minutes, the thawed FFP should be returned without delay to the Blood Bank for placement into controlled storage (i.e. "the 30 minute rule" applies).

The decision to accept unused units of thawed FFP or ELP back into the inventory for later re-use, after they have been issued to a clinical area, is the responsibility of the hospital transfusion service. This is not recommended practice unless the component has been maintained either within controlled storage conditions at all times e.g. in a validated transport container, theatre or ward blood refrigerator or has been held at room temperature outside of controlled storage for less than 30 minutes. If there is any doubt as to the suitability of returned blood components then they should be discarded.

If a thawed plasma component has been out of controlled storage for more than 30 minutes and there is no prospect of imminent transfusion, it should be returned to Blood Bank, for safe disposal and to ensure the transfusion record is accurate.

Section 3
Risks Associated With Managing Extended Life Plasma

Each health service in consultation with their HTC must decide if local circumstances justify the use of ELP. This should follow consideration of the likely benefits and possible risks associated with the use of plasma components.

Health services that decide to use ELP shall maintain current documentation regarding the decision to do so and evidence of its regular on-going review. This will include a record of the indications and contradictions for using ELP in their local setting along with consideration of any potential side effects and hazards. It should also be recognised that the manner in which ELP is used may vary according to different clinical circumstances e.g. cardiac, trauma or those on warfarin reversal.

Table 3 outlines the major risks associated with managing plasma components and provides mitigation strategies for these:

Table 3: Associated Risks Table

Activity	Potential risk	Mitigation strategies
Receipt	Damage during transport or following receipt	Inspect on receipt Unpack with care and avoid excessive or harsh handling
	Temperature fluctuations during transport	Ensure FFP received frozen and packed appropriately
Frozen Storage (at or below -25°C)	Temperature fluctuations	Store only in facilities that meet and are maintained to the requirements of AS3864
	Storage failure	Storage facilities meet AS3864
	Dirty surfaces	Defrost and clean regularly
	Pinholes or cracks in plastic	Monitor for manufacturer faults Store appropriately, avoid excessive or harsh handling
Thawing in the laboratory	Pinholes or cracks in plastic	Place in a clean sealable plastic bag during thawing if not in vacuum sealed bags
	Thawing temperature fluctuations	Monitor temperature of plasma thawer
	Duration of thawing exceeded	Remove from thawer as soon as the entire contents are visibly liquefied
	Dirty thawing equipment	Use clean, well maintained thawing equipment
	Leaking or burst bag	Discard bag as biohazard Update manual or electronic records

Activity	Potential risk	Mitigation strategies
Post-thaw Storage (at 2-6°C)	Incorrect storage temperature	Store only in facilities that meet and are maintained to the requirements of AS3864
	Dirty surfaces	Clean regularly
	Storage time exceeded: • FFP • ELP	 Use within 24 hours of thawing Use within 5 days of thawing
	Dual inventory (mix up of components)	Robust inventory management practices
Labelling with new component code (CODABAR 19590 in Australia)	Component code not modified to ELP	Standard operating procedure Update electronic or manual records with modified component type and appropriate expiry date
	Label not attached	Standard operating procedure
	Expiry date not modified	Standard operating procedure
Traceability	Manufacturing process not recorded	All manufacturing steps performed by the transfusion provider to be tracked using manual worksheets or electronic record
	Inability to trace for component recall purposes	Final disposition of thawed FFP plasma components to be recorded on worksheet or electronically
Transport to clinical area	Incorrect transport conditions	Validated transport process If outside of transport temperature range discard component as a biohazard waste
Management of component returned from clinical area	Incorrect storage conditions	Component must not be used unless there is clear evidence of appropriate storage during time outside of the laboratory's control
Adverse Reactions	Transfusion reaction or adverse outcome	Report, investigate and review all adverse reactions according to local policies If an adverse reaction is suspected to be the result of bacterial contamination: • perform blood cultures on the residues of all available transfused components • perform blood cultures on the patient • notify the Blood Service
Wastage	Increased wastage of thawed plasma components	Monitor wastage and report to hospital transfusion committee as a key performance indicator

Section 4
Thawing, Storage and Labelling Of Extended Life Plasma

4.1 Materials and equipment

- Dedicated waterbath or plasma thawer maintained between 30-37°C
- Clip-lock (press seal / snap-lock / resealable bags) (see below)
- Approved refrigerated storage equipment (refrigerator / freezer) that meets the requirements of, and is maintained, in accordance with AS 3864.2

4.2 Records/forms

- Institutional-specific forms or worksheets for documentation
- Where possible the laboratory information system should accommodate the component and allow for modifications including extended expiry date of ELP
- Labels (approved adhesive label stock / tie-on luggage labels) to indicate component type, storage conditions, expiry date and time, and component specific limitations as applicable

4.3 Quality control

- Daily temperature check of storage and thawing equipment
- Weekly cleaning (or more frequently if required) of plasma thawing waterbath or equipment
- Ensure that water bath / thawer temperature stays within specifications (30-37°C) during thawing

4.4 Procedures

Thawing FFP	
1	Place FFP in a sealable plastic bag (to protect bag ports from water); if FFP is supplied vacuum sealed by the Blood Service, no further plastic barrier is required Use of a second plastic layer facilitates recognition of a leak in the primary packaging and prevents contamination of either the component or the water bath
2	Place the FFP in a waterbath or dedicated plasma thawer at 30-37°C; do not allow ports to become submerged if in a water bath
3	The FFP should remain in the water bath only for as long as it takes to thaw and normally no more than 30 minutes The thawing time will vary according to the temperature of the water bath, the volume of the FFP unit(s) and how many units are being thawed at once
4	Immediately remove bag from waterbath (or thawing device) once plasma is thawed
5	Inspect bag for evidence of breakage, clots, fibrin or turbidity

Storage and shelf-life of Thawed FFP	
1	Once thawed, FFP must either be infused or maintained in continuous refrigerated storage (at 2-6°C) for up to 24 hours or may be converted to **ELP** (see below)
2	A record of the time and date of thawing and the time and date of expiration must be kept
3	At or before the point of issue the thawed FFP should be allocated to a specific patient
4	When allocating to a specific patient, a label must be applied to the thawed component (NPAAC Requirements); the label may be applied directly to the bag as an adhesive secondary label or as a luggage label tied to the bag
5	Clinical staff receiving the component must be educated to recognise the modified expiration date recorded on either the adhesive secondary label or tied-on luggage label
6	Place the thawed FFP in an approved blood refrigerator or cool room (at 2-6°C) until issue or expiry

Storage and shelf-life of ELP	
1	Once thawed ELP must either be infused or maintained in continuous storage at 2-6°C for up to 5 days from the time of thawing
2	A record of the time and date of thawing and the time and date of expiration must be kept
3	At or before point of issue ELP should be allocated to a specific patient
4	When allocating to a specific patient, a label must be applied to the thawed component (NPAAC requirements); the label may be applied directly to the bag as an adhesive secondary label or as a luggage label tied to the bag
5	Clinical staff receiving the component must be educated to recognise the modified expiration date recorded on either the adhesive secondary label or tied-on luggage label
6	Place the ELP in an approved blood refrigerator (2-6°C) or cool room until issue or expiry ELP may be held in inventory

Conversion of FFP to ELP	
1	If thawed FFP is not transfused within 24 hours, it may be converted to ELP, which: • expires 5 days from the day of thawing • is stored at 2-6°C • has reduced amounts of factors V, VII and VIII
2	Convert thawed FFP to ELP with appropriate expiry date and time (day of thawing = day 1; expiry time 23:59 at day 5)
3	Modify component type in electronic or manual records
4	Apply an appropriate label that obscures the existing component type (FFP), and storage conditions and states the current component type (ELP), storage conditions and expiry (see figure 1)
5	At or before the point of issue ELP should be allocated to a specific patient
6	ELP may be held in inventory or allocated to a specific patient as required

Dispatch of FFP or ELP	
1	Remove the unit to be issued from the blood refrigerator or cool room
2	The final component must be inspected for evidence of breakage, clots, fibrin or turbidity, at the time of issuing; if any of these are detected, the component must be discarded
3	Ensure person picking up the component verifies the patient's information where necessary
4	Update electronic and or manual records with patient and issue details
5	Provide a hard copy report for the patient's case notes

Expiry of FFP or ELP	
1	Remove the expired component from inventory
2	Update the electronic and manual records to indicate expiry and final fate of component
3	Where the transfusion service provider participates in the NBA's *BloodNet* a report should be sent
4	Dispose of the expired component as biohazard waste

Section 5
Labelling Requirements For Extended Life Plasma

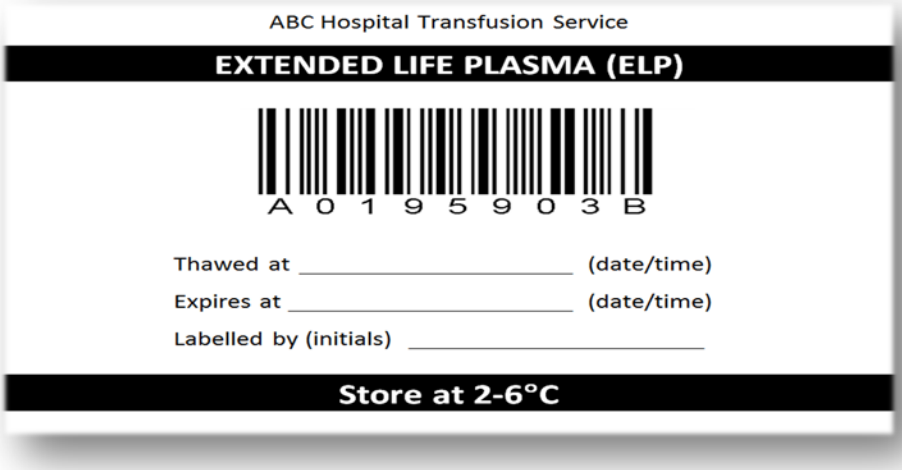
5.1 Requirement for relabelling

If thawed FFP is not used within 24 hours of thawing or it is to be held in the inventory as ELP (for up to 5 days from thawing) it must be relabelled accordingly, using an appropriate component label, reflecting the change in component name.

5.2 Extended Life Plasma label

A label must be attached to the ELP showing the change in component name (*Extended Life Plasma*), new component code, thawing date/time, expiry date/time and identity (e.g. initials) of person who relabelled the unit.

*Figure 1: Example of an Extended Life Plasma (ELP) label**



** This example label shows the Australian component code of 19590 (in CODABAR format). It should be noted that the barcode also includes start and stop codes A0 and 3B respectively.*

5.3 Patient Label

Following allocation to a patient and before release for transfusion, the component must be labelled in accordance with section 1.2.4 of the ANZSBT *Guidelines for pretransfusion laboratory practice***.**

Section 6

Transfusion Service Provider Self-Assessment Tool

The following table provides a self-assessment tool to assist hospital transfusion services in the procedural requirements for managing an inventory of thawed fresh frozen plasma and ELP.

Requirements	Complies?		Comments
Guidelines for use of FFP	Yes ☐	No ☐	
SOP for thawing, storage, labelling and issue of FFP / ELP	Yes ☐	No ☐	
SOP for maintenance of plasma thawer / water bath	Yes ☐	No ☐	
Freezer storage complies with AS 3864.2	Yes ☐	No ☐	
Refrigerated storage complies with AS 3864.2	Yes ☐	No ☐	
Cleaning and maintenance of storage equipment occurs in accordance with:			
• AS 3864.2	Yes ☐	No ☐	
• Manufacturer's specifications	Yes ☐	No ☐	
• NATA *ISO 15189 Medical Testing Field Application Document*	Yes ☐	No ☐	

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The *Blood Component Information – Circular of Information* (2012) produced by the Australian Red Cross Blood Service was used as the primary reference for technical information in preparing this document. A number of other information sources were also used in developing these guidelines and these are listed below:

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