

**Comparison of Recovered Plasma to Source Plasma for Viral Safety
Based on Regulatory requirements and Industry Standard specifications**

Donor - General Population

Recovered Plasma Center		Source Plasma Center
<p>Proposed QSEAL standard specification for Recovered Plasma, Supplier (including infrequent source plasma collected by blood establishments)</p> <p>Certification: Each <u>manufacturer</u> needs to implement processes to assure the Recovered Plasma Supplier is in compliance with this specification. A PPTA approved checklist shall be developed for this purpose.</p> <p>The documented compliance of recovered plasma suppliers with the Recovered Plasma Specification shall be verified by PPTA during QSEAL certification- and re-certification audits of <u>fractionators</u>.</p> <p>Furthermore, an updated list of all recovered plasma suppliers with indication of the standard compliance status and the date of the most recent verification audit could be provided to PPTA by the fractionators e.g. annually.</p>		<p>iQPP certification process in place</p>
<p>Age limit according to national regulations</p>		<p>Age is 18 or older but less than 65</p>
<p>Infrequent collection according to whole blood collection criteria</p>		<p>Frequent collection</p>
<p>System of donor identification</p>		<p>System of donor identification</p>
<p>All donors</p>		<p>Community based donors</p>
<p>First time and repeat donors</p>		<p>Qualified Donors only</p>

Local Donor Deferral Registry		National Donor Deferral Registry (US only), Local Donor Deferral Registry, (EU and US)
Self Exclusion on High Risk Behavior		Verify knowledge on High Risk Behavior Self Exclusion on High Risk Behavior
N/A		Physical (first time and annually)
Donor Vital Signs: Heart Rate Blood Pressure Temperature Hemoglobin/Hematocrit N/A		Donor Vital Signs: Heart Rate Blood Pressure Temperature Hematocrit Total Protein
Medical History Questionnaire		Medical History Questionnaire
Testing of donations		
Serology Testing according to national regulations (unit testing) Anti-HIV 1&2 HBsAg Anti –HCV NAT Testing according to national regulations	HTLV 1 & 2* Hbcore* Chagas*	Serology Testing according to national regulations (unit testing) Anti-HIV 1&2 HBsAg Anti-HCV NAT Testing according to national regulations
Viral Marker Rate Standard Under development		Viral Marker Rate Standard Use current iQPP standard
Before pooling or at pool level manufacturers have to ensure that the following testing is performed:		
Serological testing/NAT Testing according to national regulations According to PPTA's voluntary standards, fractionators ensure that NAT testing is perform for: HIV 1 HBV HCV Parvo B-19		

*Not required for further manufacturing, center typically does not ship if positive

Residual Risk

Utilize risk calculation model developed by PMF Task Force to show that residual risk for Recovered Plasma is similar to Normal Source plasma.

Units Released and Shipped to Manufacturer

Manufacturing Plant - Pooling

Recovered Plasma

N/A

Look back on Positive Test Results
Post Donation Information

Incoming Residual Risk = XX
(ref. to PMF calculations)

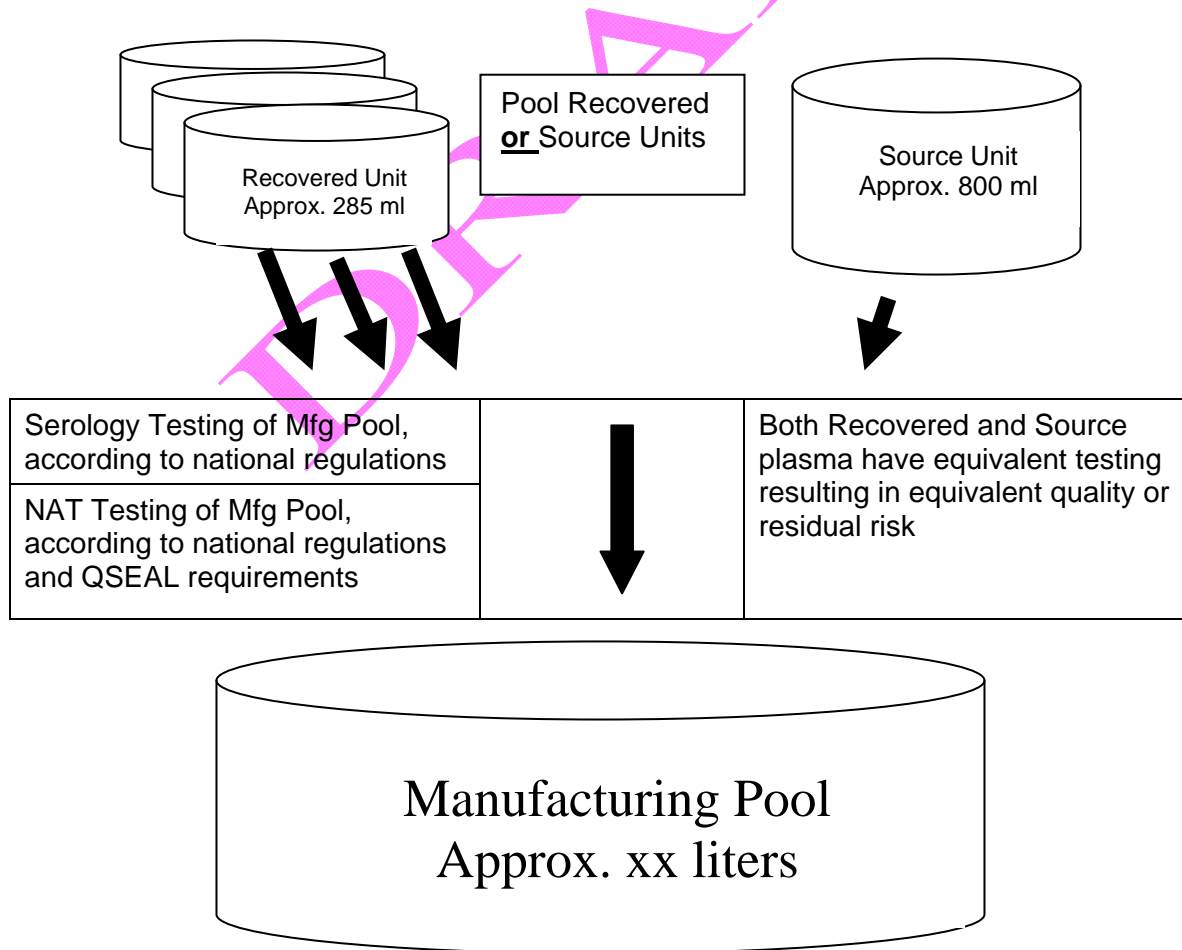
Source Plasma

60 day Inventory hold

Lookback on Positive Test Results
Post Donation Information

Incoming Residual Risk = XX
(ref. to PMF calculations)

Residual Risk for Recovered Plasma is similar to Source Plasma



Residual Risk

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Comments are due by Friday, April 16, 2010. Please send your comments to Michelle Mason @ mmason@pptaglobal.org