

DATE: February 16, 2010 **Via E-Mail and Web Posting**
Reference No: QSEAL10009

TO: PPTA Global Board of Directors
PPTA Global Management Committee
PPTA European Board of Directors
PPTA North America Board of Directors
PPTA Source Board of Directors
PPTA QSEAL Task Force

FROM: Jan M. Bult, President, PPTA

SUBJECT: COMMENT PERIOD OPEN FOR ADDITION OF RECOVERED PLASMA SPECIFICATION to QSEAL

Urgent Handle & Confirm Review & Comment FYI As Requested

The PPTA Board of Directors has approved the draft of the new Recovered Plasma Specification to be posted for industry and public comment. The draft Specification has been developed to allow the QSEAL program to extend to manufacturers using Recovered Plasma as a starting material for the manufacture of plasma protein therapies. The document entitled, "Recovered Plasma Specification" includes the minimum acceptance criteria that are to be allowed for use of Recovered Plasma in the manufacture of plasma protein therapies and assigns where adherence to the criteria is expected, i.e., by the collector or by the manufacturer. The document entitled, "Comparison of Recovered Plasma to Source Plasma for Viral Safety Based on Regulatory requirements and Industry Standard specifications" provides a comparison between safeguards employed regardless of the plasma source and the similarity in safety at the manufacturing pool level. This document also describes that the expectations for compliance of Recovered Plasma suppliers with the Recovered Plasma Specification shall be verified by PPTA during QSEAL audits of fractionators.

In accordance with the procedures for developing a PPTA Voluntary Standard, the public comment period will be open for sixty days from the date the draft documents are posted on the PPTA website. After the close of the comment period, all information received related to the Recovered Plasma Specification will be reviewed. If comments received result in substantive changes to the Specification, there may be another comment period. If there are no or minor changes based on comments, the change to QSEAL to include the Recovered Plasma Specification will be implemented. We will give adequate notice for the implementation period of the Recovered Plasma Specification.

The Recovered Plasma Specification and related documents are available for download and comment at www.pptaglobal.org. We encourage your early review and are looking forward to your feedback. **Please send your feedback to Michelle Mason at mmason@pptaglobal.org by Friday, April 16th.**

If you have any questions, please contact us at the Association.