

IQPP Cross Donation Management Standard Implemented 2010

I. Introduction

The ability to manufacture and provide life-saving plasma protein therapies is dependent on having a steady supply of quality plasma from committed, healthy plasma donors. The health and safety of donors is of the highest importance. Regulations and standards have been developed to screen donors prior to donation, to monitor their health periodically during their donation tenure and to limit the volume of plasma at each donation as well as the number of donations in a given period of time. Operating under these Standards helps ensure that donors will remain healthy.

A donor may misunderstand the reasons for limiting the number of donations per week or another given period of time. Rarely, a donor may attempt to donate more often than is allowed. While these are rare occurrences, it is necessary to take measures to protect the health of the donor and minimize the risk of cross donation. For this reason, PPTA has developed the IQPP Cross Donation Management Standard.

II. Definitions

Cross Donation –	A donation pattern in which a donor exceeds the maximum allowable donation frequency by donating at more than one plasma center
Donor Recruitment Area –	A documented, geographic area pre-determined by a plasma center and included in its systems, from which plasma donors are recruited (See IQPP Community-Based Donor Standard).
Donor Check Form --	Form used between companies to share donor information. The form should include the following: receiving and sending center name and address, donor name and date of birth, last four digits of donor identification number (SSN or INS number, where applicable) [in appropriate jurisdiction], deferral status, date of last two donations. An example of an equivalent system could be a computerized system sharing information required in the Donor Check Form.

III. Standard

Each center shall complete a Donor Check Form (example included below), or equivalent system, listing all Applicant Donors (A1 and AR)¹ that presented for donation in the center that day, and submit to all centers within its Donor Recruitment Area (DRA) no later than the end of each day of center operation. The required information must be submitted to all centers within the DRA such that the receiving center should receive the information on the same calendar day that the sending center transmits it. Response should be returned by the receiving centers as soon as possible but no more than one operating day after receipt of form. Forms prepared and received by centers in the DRA must be retained for a minimum of six months.² Procedures for review of forms and follow-up actions should be incorporated into a company's quality system and subject to internal quality audits.

Donors must not exceed the allowable limits for donating, per regulatory requirements. If a donor is found to be donating in more than one plasma center, they will fall into one of two categories:

- Donor is active in more than one center but not exceeding allowable limits for donations.
- Donor is active in more than one center and is exceeding the allowable limit for donations.

A donor who is found to be actively donating in more than one center but not exceeding the maximum allowable limits will be informed about the health risks of donating more frequently than is allowed by regulation and the reasons for the center's concerns for the donor's health if *cross donating* should occur. A company must have a policy in place stating how it will prevent a donor found to be an active donor in more than one center from donating more often than allowed.

A donor who is found to be *cross donating* will be permanently deferred.

This Standard should not be interpreted in such a way that it dissuades centers from adopting more stringent requirements. Where applicable, a fingernail dye identification (using fluorescent dye), or similar system, can be used as a method to help avoid *cross-donation*.

Companies must have a process in place to notify all plasma centers, of which they are aware, within the DRA, that they are opening a new center 30 days prior to the scheduled opening date.

¹ See definition of "Applicant Donor" in IQPP Qualified Donor Standard

² The six month period is to be maintained for auditing purposes.

IV. Inspection and Compliance Verification

During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to the Cross Donation Management Standard. They shall then review the procedures for compliance to the Standard.

During the IQPP Plasma Center Audit, auditors shall review records that relate to the Cross Donation Management Standard as well as track through the documentation of several donors for compliance to the Standard. Irregularities in the completion, sharing or follow-up action may result in issue-driven IQPP audits at each of the centers in the DRA.

IQPP CROSS DONATION MANAGEMENT STANDARD

Revision History

Date	History
2009	Standard developed.
February 2010	Implementation of standard began.