
# IQPP Professional Plasma Collection Facility Standard

**Version 3.0**
**Approved June 25, 2014**

PPTA
Plasma Protein Therapeutics Association

## Background

The IQPP Professional Plasma Collection Facility Standard is part of a series of standards that comprise the Plasma Protein Therapeutics Association (PPTA) IQPP Standards Program. PPTA's Voluntary Standards Program provides global leadership for the plasma protein industry's goal of continuous improvement with a focus on safety and quality from the donor to the patient.

This voluntary IQPP Standard was developed by the PPTA IQPP Standards Committee, and was approved by the PPTA Source Board of Directors on June 25, 2014. The current version of this standard supersedes version 2.0 in its entirety.

For questions about this PPTA Voluntary Standard contact IQPP@pptaglobal.org. For more information about the IQPP Standards Program or PPTA, visit www.pptaglobal.org.


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## 1. Introduction
People around the world depend on therapeutics derived from human plasma proteins to treat conditions such as hemophilia, immune disorders and other diseases or injuries. The ultimate safety of these therapeutics is critically dependent upon the quality of the source material from which they are derived.

This IQPP Standard is part of a series of standards that comprise the PPTA IQPP Voluntary Standards Program. For more information about the program, visit www.pptaglobal.org.

## 2. Scope
This standard applies to facilities that collect Source Plasma.

## 3. Purpose
This IQPP standard helps to promote safe products by ensuring an environment where dedicated donors feel comfortable as they approach the facility and engage in the donation process. Compliance with this standard also helps promote the acceptance of the IQPP-certified plasma center by the surrounding community. Plasma collection facilities serve as ambassadors of the industry to regulators, patient groups and the public at large.

The purpose of this standard is to provide requirements for consistent levels of presentation and organizational flow at a Source Plasma collection facility.

## 4. Terms and Definitions
### 4.1. GMP
Good Manufacturing Practices

### 4.2. Center
Facility in which Source Plasma is collected

### 4.3. Unauthorized Areas
Areas in which only Center staff and contracted individuals are allowed access and are not accessible to the public

## 5. Requirements

**5.1.** The Center shall meet all GMP requirements regarding facility maintenance and appearance.

**5.2.** The Center shall be well maintained on the outside and inside. The exterior of the Center should not show any signs of loss of structural integrity. Windows and doors shall be maintained in good repair. Open windows shall be adequately screened in order to prevent insects, debris, etc. from entering the Center.

**5.3.** The area outside the Center should be free of trash, litter and debris. There should not be persons loitering outside the Center.

> *NOTE: Centers should have a policy stating that littering and loitering about the Center are prohibited, and that smoking, while prohibited in the center, may be permitted about the center only in designated smoking areas.*

The area around the dumpsters shall be kept free of waste.

**5.4.** The Center shall operate in a manner that ensures donor and staff safety. This includes ensuring adequate lighting in applicable parking lots and around the entrances and exits of the Center.

**5.5.** The entrance to the Center shall control the flow of donors and prevent public access to the unauthorized areas of the Center. Donors should not overflow outside the waiting area into aisles, doorways, outdoors or other areas of the Center. All areas of the Center shall be configured to provide for safe and proper operation.

**5.6.** Signage shall be professional in appearance and appropriately maintained. Temporary signs such as posters and banners for promotional campaigns shall be professional in appearance and also appropriately maintained.

**5.7.** All surfaces (walls, floor, ceiling) shall be maintained in a clean and sanitary manner and be kept in good repair. Adequate interior lighting shall also be maintained.

**5.8.** There shall be separate restroom facilities for donors and Center staff. All restrooms shall be kept clean and in good repair. Donor restrooms shall be easily accessible for the donors. Adequate supplies for hand washing and sanitary purposes shall be made available in all restrooms and appropriate areas. Cleaning supplies shall be maintained in an appropriate sanitary condition.

**5.9.** Storage areas shall be kept clean and at their appropriate temperature levels as well as be adequate in size to contain all supplies necessary for Center operation. Supplies shall be kept in areas of the Center accessible only to authorized personnel. The infectious waste area shall also be accessible only to authorized personnel.

**5.10.** Donors shall not have access to manufacturing records, supplies, plasma units and corresponding samples. The Center shall handle Donor Record Files and information in a manner that maintains confidentiality and prevents unauthorized access.

## 6. Audit and Compliance Verification

During the IQPP Plasma Center Audit, auditors shall tour the Center and note any signs of deterioration or unsafe conditions as they pertain to the Professional Plasma Collection Facility Standard. In addition, auditors shall review records pertaining to cleaning logs and storage area temperature logs.