

International Quality Plasma Program Standard

for

Professional Plasma Collection Facility

**Implemented 1991
Revised 2009**

Version 2.0

Document #019437

IQPP Professional Plasma Collection Facility Standard Implemented 1991 Revised January 2009

I. 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.

PPTA Source IQPP-certified plasma centers must maintain an appearance expected of a professional facility.

The Professional Plasma Collection Facility 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.

II. Definitions

GMP - Good Manufacturing Practices

Unauthorized areas - Areas in which only plasma center staff and contracted individuals are allowed access and are not accessible to the public.

III. Standard

The plasma center must have been licensed/certified by their corresponding regulatory authority before an IQPP certificate will be issued. The plasma center must meet all GMP requirements regarding facility maintenance and appearance.

The plasma center must be well maintained on the outside and inside. The exterior of the building should not show any signs of loss of structural integrity. Windows and doors must be maintained in good repair. Open windows must be adequately screened in order to prevent insects, dust, etc from entering the plasma center.

The area outside the plasma center should be free of trash, litter and debris. There should not be persons loitering outside the plasma center. Plasma centers should have a policy stating that littering, loitering and smoking in and about the plasma center is prohibited. The area around the dumpsters must be kept free of waste.

The plasma center should 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 facility.

Entrance to the building must control the flow of donors into the plasma center and prevent public access to the unauthorized areas of the building. Donors should not overflow outside the waiting area into aisles, doorways, outdoors or other areas of the facility. All areas of the plasma center must be configured to provide for safe and proper operation.

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

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

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

The temperature of the plasma center must be maintained at a level that is comfortable for donors and staff. Storage areas must be kept clean and at their appropriate temperature levels as well as be adequate in size to contain all supplies necessary for plasma center operation. Supplies must be kept in areas of the plasma center accessible only to authorized personnel. The infectious waste area must also be accessible only to authorized personnel.

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

IV. Inspection and Compliance Verification

During the IQPP Plasma Center Audit, auditors shall tour the plasma 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 temperature and cleaning logs.

IQPP PROFESSIONAL PLASMA COLLECTION FACILITY STANDARD

Revision History

Date	History
1991	Standard implemented through IQPP Audit Report Form
	Requirement of separate facilities for staff use added.
	Requirement for cleaning materials added.
	Requirements for temporary signs for promotional campaigns added.
7/2006	Several questions redundant to areas already audited by other regulatory authorities removed.
January 2009	Standard put into written format.
January 2009	Name changed from "Professional Medical Facility Criteria Standard"
January 2009	Questions regarding interior and exterior appearance and safety features of facility added.