the responsible physician may delegate to a physician substitute the activities described in §630.15(b)(1), (2), and (5). The responsible physician is not required to be present at the collection site when the physician substitute performs these activities under supervision.

(4) *Infrequent plasma donors.* (i) For infrequent plasma donors other than those described in paragraph (c)(4)(ii) of this section, the responsible physician may delegate to a trained person the activities listed in paragraphs (b)(1)(i) through (iii) and (b)(1)(v) of this section and the informed consent requirements described in §630.15(b)(2). The responsible physician or a physician substitute need not be present at the collection site when any of these activities are performed, provided that the responsible physician has delegated oversight of these activities to a trained person who is not only adequately trained and experienced in the performance of these activities but also adequately trained and experienced in the recognition of and response to the known adverse responses associated with blood collection procedures. However, the responsible physician must not delegate:

(A) The examination and determination of the donor's health required in §630.10(f)(2) for donors with blood pressure measurements outside specified limits, or in §630.15(b)(7) for certain donors who have experienced red blood cell loss; or

(B) The determination of the health of the donor required in §630.10(f)(4).

(ii) For infrequent plasma donors who are otherwise ineligible or are participating in an approved immunization program, the responsible physician may delegate only in accordance with paragraphs (c)(1) through (3) of this section.

(d) *Must rapid emergency medical services be available*? Establishments that collect blood or blood components must establish, maintain, and follow standard operating procedures for obtaining rapid emergency medical services for donors when medically necessary. In addition, establishments must assure that an individual (responsible physician, physician substitute, or trained person) who is currently certified in cardiopulmonary resuscitation is located on the premises whenever collections of blood or blood components are performed.

§ 630.10 General donor eligibility requirements.

(a) *What factors determine the eligibility of a donor*? You, an establishment that collects blood or blood components, must not collect blood or blood components before determining that the donor is eligible to donate or before determining that an exception to this provision applies. To be eligible, the donor must be in good health and free from transfusion-transmitted infections as can be determined by the processes in this subchapter. A donor is not eligible if the donor is not in good health or if you identify any factor(s) that may cause the donation to adversely affect:

(1) The health of the donor; or

(2) The safety, purity, or potency of the blood or blood component.

(b) *What educational material must you provide to the donor before determining eligibility*? You must provide educational material concerning relevant transfusion-transmitted infections to donors before donation when donor education about that relevant transfusion-transmitted infection, such as HIV, is necessary to assure the safety, purity, and potency of blood and blood components. The educational material must include an explanation of the readily identifiable risk factors closely associated with exposure to the relevant transfusion-transmitted infection. You must present educational material in an appropriate form, such as oral, written or multimedia, and in a manner designed to be understood by the donor. The educational material must instruct the donor not to donate blood and blood components when a risk factor is present. When providing educational material to donors under this section, you may include in those materials the information required to be provided to donors under paragraph (g)(2)(ii)(E) of this section.

(c) *When must you determine the eligibility of a donor*? You must determine donor eligibility on the day of donation, and before collection. Except:

(1) When a donor is donating blood components that cannot be stored for more than 24 hours, you may determine the donor's eligibility and collect a sample for testing required under § 610.40 of this chapter, no earlier than 2 calendar days before the day of donation, provided that your standard operating procedures address these activities.

(2) In the event that, upon review, you find that a donor's responses to the donor questions before collection were incomplete, within 24 hours of the time of collection, you may clarify a donor's response or obtain omitted information required under paragraph (e) of this section, provided that your standard operating procedures address these activities.

(d) *How must you determine the eligibility of a donor*? You must determine the donor's eligibility before collection of blood or blood components, by the following procedures:

(1) You must consult the records of deferred donors maintained under § 606.160(e)(1) and (2) of this chapter. Exception: If pre-collection review of the record described in § 606.160(e)(2) of this chapter is not feasible because you cannot consult the cumulative record at the collection site, you must consult the cumulative record prior to release of any blood or blood component prepared from the collection.

(2) Assure that the interval since the donor's last donation is appropriate;

(3) Assess the donor's medical history; and

(4) Perform a physical assessment of the donor.

(e) *How do you assess the donor's medical history*? Before collection you must conduct a medical history interview as described in this section to determine if the donor is in good health; to identify risk factors closely associated with exposure to, or clinical evidence of a relevant transfusion-transmitted infection; and to determine if there are other conditions that may adversely affect the health of the donor or the safety, purity, or potency of the blood or blood components or any product manufactured from the blood or blood components. Your assessment must include each of the following factors:

(1) Factors that make the donor ineligible to donate because of an increased risk for, or evidence of, a relevant transfusion-transmitted infection. A donor is ineligible to donate when information provided by the donor or other reliable evidence indicates possible exposure to a relevant transfusion-transmitted infection if that risk of exposure is still applicable at the time of donation. Information and evidence indicating possible exposure to a relevant transfusion-transmitted infection include:

(i) Behaviors associated with a relevant transfusion-transmitted infection;

(ii) Receipt of blood or blood components or other medical treatments and procedures associated with possible exposure to a relevant transfusion-transmitted infection;

(iii) Signs and/or symptoms of a relevant transfusion-transmitted infection;

(iv) Institutionalization for 72 hours or more consecutively in the past 12 months in a correctional institution;

(v) Intimate contact with risk for a relevant transfusion-transmitted infection; and

(vi) Nonsterile percutaneous inoculation.

(2) Other factors that make the donor ineligible to donate. A donor is ineligible to donate when donating could adversely affect the health of the donor, or when the safety, purity, or potency of the blood or blood component could be affected adversely. Your assessment of the donor must include each of the following factors:

(i) Symptoms of a recent or current illness;

(ii) Certain medical treatments or medications;

(iii) Travel to, or residence in, an area endemic for a transfusion-transmitted infection, when such screening is necessary to assure the safety, purity, and potency of blood and blood components due to the risks presented by donor travel and the risk of transmission of that transfusion-transmitted infection by such donors;

(iv) Exposure or possible exposure to an accidentally or intentionally released disease or disease agent relating to a transfusion-transmitted infection,

if you know or suspect that such a release has occurred;

(v) Pregnancy at the time of, or within 6 weeks prior to, donation;

(vi) Whether, in the opinion of the interviewer, the donor appears to be under the influence of any drug, alcohol or for any reason does not appear to be providing reliable answers to medical history questions, or if the donor says that the purpose of donating is to obtain test results for a relevant transfusion-transmitted infection; and

(vii) The donor is a xenotransplantation product recipient.

(f) *How do you perform a physical assessment of the donor*? You must determine on the day of donation, and before collection that the donor is in good health based on the following, at a minimum:

(1) *Temperature*. The donor's oral body temperature must not exceed 37.5 °C (99.5 °F), or the equivalent if measured at another body site;

(2) *Blood pressure*. The donor's systolic blood pressure must not measure above 180 mm of mercury, or below 90 mm of mercury, and the diastolic blood pressure must not measure above 100 mm of mercury or below 50 mms of mercury. A donor with measurements outside these limits may be permitted to donate only when the responsible physician examines the donor and determines and documents that the health of the donor would not be adversely affected by donating.

(3) *Hemoglobin or hematocrit determination*. You must determine the donor's hemoglobin level or hematocrit value by using a sample of blood obtained by fingerstick, venipuncture, or by a method that provides equivalent results. Blood obtained from the earlobe is not acceptable.

(i) Allogeneic donors must have a hemoglobin level or hematocrit value that is adequate to assure donor safety and product potency. The following minimum standards apply.

(A) Female allogeneic donors must have a hemoglobin level that is equal to or greater than 12.5 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 38 percent. Recognizing that lower levels are also within normal limits for female donors, you may collect blood from female allogeneic donors who have a hemoglobin level between 12.0 and 12.5 grams per deciliter of blood, or a hematocrit value between 36 and 38 percent, provided that you have taken additional steps to assure that this alternative standard is adequate to ensure that the health of the donor will not be adversely affected due to the donation, in accordance with a procedure that has been found acceptable for this purpose by FDA.

(B) Male allogeneic donors must have a hemoglobin level that is equal to or greater than 13.0 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 39 percent.

(ii) An autologous donor must have a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood, or a hematocrit value no less than 33 percent.

(4) *Pulse*. The donor's pulse must be regular and between 50 and 100 beats per minute. A donor with an irregular pulse or measurements outside these limits may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(5) *Weight*. The donor must weigh a minimum of 50 kilograms (110 pounds).

(6) *Skin examination*. (i) The donor's phlebotomy site must be free of infection, inflammation, and lesions; and

(ii) The donor's arms and forearms must be free of punctures and scars indicative of injected drugs of abuse.

(g) *Are there additional requirements for determining the eligibility of the donor*? You must obtain the following from the donor on the day of donation:

(1) *Proof of identity and postal address*. You must obtain proof of identity of the donor and a postal address where the donor may be contacted for 8 weeks after donation; and

(2) *Donor's acknowledgement*. (i) Prior to each donation, you must provide information to the donor addressing the elements specified in paragraphs (g)(2)(ii)(A) through (E) of this section and obtain the donor's acknowledgement that the donor has reviewed the information. You must establish procedures in accordance with § 606.100 of

this chapter to assure that the donor has reviewed this material, and provide for a signature or other documented acknowledgement.

(ii) The donor acknowledgement must not include any exculpatory language through which the donor is made to waive or appear to waive any of the donor's legal rights. It must, at a minimum clearly address the following:

(A) The donor has reviewed the educational material provided under paragraph (b) of this section regarding relevant transfusion-transmitted infections;

(B) The donor agrees not to donate if the donation could result in a potential risk to recipients as described in the educational material;

(C) A sample of the donor's blood will be tested for specified relevant transfusion-transmitted infections;

(D) If the donation is determined to be not suitable under §630.30(a) or if the donor is deferred from donation under §610.41 of this chapter, the donor's record will identify the donor as ineligible to donate and the donor will be notified under §630.40 of the basis for the deferral and the period of deferral;

(E) The donor has been provided and reviewed information regarding the risks and hazards of the specific donation procedure; and

(F) The donor has the opportunity to ask questions and withdraw from the donation procedure.

(h) *What must you do when a donor is not eligible*? You must not collect blood or blood components from a donor found to be ineligible prior to collection based on criteria in §§630.10 or 630.15, or deferred under §610.41 of this chapter or §630.30(b)(2), unless this subchapter provides an exception. You must defer donors found to be ineligible and you must notify the donor of their deferral under §630.40.

§ 630.15 Donor eligibility requirements specific to Whole Blood, Red Blood Cells and Plasma collected by apheresis.

(a) *What additional donor eligibility requirements apply when you, an establishment that collects blood or blood components, collect Whole Blood or Red Blood Cells by apheresis*?

(1) *Donation frequency must be consistent with protecting the health of the donor*.

(i) For a collection resulting in a single unit of Whole Blood or Red Blood Cells collected by apheresis, donation frequency must be no more than once in 8 weeks, and for apheresis collections resulting in two units of Red Blood Cells, the donor must not donate more than once in 16 weeks.

(ii) The limitations in paragraph (a)(1)(i) of this section apply unless the responsible physician examines the donor at the time of donation and one of the following conditions exists:

(A) The donation is for autologous use as prescribed by the donor's physician and the responsible physician determines and documents that the donation may proceed; or

(B) The donation is a dedicated donation based on the intended recipient's documented exceptional medical need and the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(2) *Therapeutic phlebotomy*. When a donor who is determined to be eligible under §630.10 undergoes a therapeutic phlebotomy under a prescription to promote the donor's health, you may collect from the donor more frequently than once in 8 weeks for collections resulting in a single unit of Whole Blood or Red Blood Cells, or once in 16 weeks for apheresis collections resulting in two units of Red Blood Cells, provided that the container label conspicuously states the disease or condition of the donor that necessitated phlebotomy. However, no labeling for the disease or condition is required under this section if:

(i) The donor meets all eligibility criteria;

(ii) The donor undergoes a therapeutic phlebotomy as prescribed by a licensed health care provider treating the donor for:

(A) Hereditary hemochromatosis; or

(B) Another disease or condition, when the health of a donor with that disease or condition will not be adversely affected by donating, and the donor's disease or condition will not adversely affect the safety, purity, and