(4) The donor's blood is tested in accordance with §610.40 of this chapter, and is negative or nonreactive, unless an exception applies under §610.40(h) of this chapter; and

(5) The donation meets other requirements in this subchapter.

(b) *What must you do when the donation is not suitable*? (1) You must not release the donation for transfusion or further manufacturing use unless it is an autologous donation, or an exception is provided in this chapter.

(2) You must defer the donor when a donation is determined to be unsuitable based on the criteria in paragraphs (a)(1) through (4) of this section.

(3) You must defer the donor of bacterially contaminated platelets when the contaminating organism is identified in accordance with §606.145(d) of this chapter as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor.

(4) You must notify the deferred donor in accordance with the notification requirements in §630.40.

§630.35 Requalification of previously deferred donors.

Establishments may determine a deferred donor to be eligible as a donor of blood and blood components if, at the time of the current collection, the donor meets the eligibility criteria in this part, except for the record of the previous deferral, and you determine that the criteria that were the basis for the previous deferral are no longer applicable. Criteria for the previous deferral are no longer applicable if the following conditions are met:

(a) The previous deferral was for a defined period of time and that time period has passed, or the deferral was otherwise temporary, such as a deferral based on eligibility criteria described in §§630.10(f)(1) through (5) or 630.15(b)(4); or

(b) For a donor deferred for reasons other than under §610.41(a) of this chapter, you determine that the donor has met criteria for requalification by a method or process found acceptable for such purpose by FDA.

Subpart C—Donor Notification

SOURCE: 80 FR 29898, May 22, 2015, unless otherwise noted.

§630.40 Requirements for notifying deferred donors.

(a) *Notification of donors.* You, an establishment that collects blood or blood components, must make reasonable attempts to notify any donor, including an autologous donor, who has been deferred based on the results of tests for evidence of infection with a relevant transfusion-transmitted infection(s) as required by §610.41(a) of this chapter; any donor who has been deferred as required under §630.30(b)(3) because their donated platelets have been determined under §606.145(d) of this chapter to be contaminated with an organism that is identified as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor; and any donor who has been determined not to be eligible as a donor based on eligibility criteria under §§630.10 and 630.15. You must attempt to obtain the results of further testing required under §610.40(e) of this chapter prior to notifying a donor of the deferral. If notification occurs prior to receipt of such results, you must also notify a deferred donor of the results of the further testing. You must notify a donor as described in paragraph (b) of this section.

(b) *Content of notification.* You must provide the following information to a donor deferred or determined not to be eligible as a donor as described in paragraph (a) of this section:

(1) That the donor is deferred or determined not to be eligible for donation and the reason for that decision;

(2) Where appropriate, the types of donation of blood or blood components that the donor should not donate in the future;

(3) Where applicable, the results of tests for evidence of infection due to relevant transfusion-transmitted infection(s) that were a basis for deferral under §610.41 of this chapter, including results of further testing as required in §610.40(e) of this chapter; and,

(4) Where appropriate, information concerning medical followup and counseling.

(c) *Time period for notification.* You must make reasonable attempts to notify the donor within 8 weeks after determining that the donor is deferred or determined not to be eligible for donation as described in paragraph (a) of this section. You must document that you have successfully notified the donor or when you are unsuccessful that you have made reasonable attempts to notify the donor.

(d) *Autologous donors.* (1) You also must provide the following information to the referring physician of an autologous donor who is deferred based on the results of tests for evidence of infection with a relevant transfusion-transmitted infection(s) or whose platelets indicate evidence of a bacterial infection that is endogenous to the bloodstream of the donor as described in paragraph (a) of this section:

(i) Information that the autologous donor is deferred based on the results of tests for evidence of infection due to relevant transfusion-transmitted infection(s), as required under §610.41 of this chapter, and the reason for that decision;

(ii) Where appropriate, the types of donation of blood or blood components that the autologous donor should not donate in the future; and

(iii) The results of tests for evidence of infection due to relevant transfusion-transmitted infection(s), that were a basis for deferral under §610.41 of this chapter, including results of further testing as required in §610.40(e) of this chapter.

(2) You must make reasonable attempts to notify the autologous donor's referring physician within 8 weeks after determining that the autologous donor is deferred as described in paragraph (a) of this section. You must document that you have successfully notified the autologous donor's referring physician or when you are unsuccessful that you have made reasonable attempts to notify the physician.

[66 FR 31176, June 11, 2001. Redesignated and amended at 80 FR 29898, May 22, 2015]

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Subpart A—Whole Blood

Subpart B—Red Blood Cells

Subpart C—Platelets

Subpart D—Plasma

Subpart E [Reserved]

Subpart F—Cryoprecipitate

Subpart G—Source Plasma