

shall quarantine Whole Blood, blood components, Source Plasma and Source Leukocytes held at that establishment except as provided in paragraph (c) of this section.

(b) *Further testing and notification of consignees of results.* Blood establishments that have collected Whole Blood, blood components, Source Plasma or Source Leukocytes from a donor as described in paragraph (a) of this section shall perform a licensed, more specific test for HIV on the donor's blood, and in the case of distributed products, further shall notify the consignee(s) of the results of this test, within 30 calendar days after the donor's repeatedly reactive test. Pending the availability of a licensed, more specific test for HIV-2, a second, different screening test for antibody to HIV-2 shall be used along with a licensed, more specific test for HIV-1.

(c) *Exemption from quarantine.* Products intended for transfusion need not be held in quarantine if a determination has been made that the Whole Blood, blood components, Source Plasma or Source Leukocytes was collected more than 12 months prior to the donor's most recent negative antibody screening test when tested in accordance with § 610.45. Pooled Source Plasma and Source Leukocytes are exempt from quarantine.

(d) *Release from quarantine.* Whole Blood, blood components, Source Plasma and Source Leukocytes intended for transfusion or further manufacture which have been quarantined under paragraph (a) of this section may be released if the donor is subsequently tested for antibody to HIV as provided in paragraph (b) of this section and the test result is negative, absent other informative test results.

(e) Actions under this section do not constitute a product recall as defined in § 7.3(g) of this chapter.

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**§ 610.47 "Lookback" notification requirements for transfusion services.**

(a) Transfusion services that are not subject to the Health Care Financing Administration's regulations on conditions of Medicare participation for hospitals (42 CFR part 482) are required to take appropriate action in accordance

with paragraphs (b) and (c) of this section when a recipient has received Whole Blood or blood components from a donor determined to be unsuitable when tested for human immunodeficiency virus (HIV) infection in accordance with § 610.45 and the results of the additional tests as provided for in § 610.46(b) are positive.

(b) *Notification of recipients of prior transfusion.* If the transfusion service has administered Whole Blood or blood components as described in paragraph (a) of this section, the transfusion service shall notify the recipient's attending physician (physician of record) and ask him or her to inform the recipient of the need for HIV testing and counseling. If the physician is unavailable or declines to notify the recipient, the transfusion service shall notify the recipient and inform the recipient of the need for HIV testing and counseling. The notification process shall include a minimum of three attempts to notify the recipient and be completed within a maximum 8 weeks of receipt of the result of the licensed, more specific test for HIV. The transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling, and shall document the notification or attempts to notify the attending physician or the recipient, pursuant to § 606.160 of this chapter.

(c) *Notification to legal representative or relative.* If the transfusion recipient has been adjudged incompetent by a State court, the transfusion service or physician must notify a legal representative designated in accordance with State law. If the transfusion recipient is competent, but State law permits a legal representative or relative to receive the information on the recipient's behalf, the transfusion service or physician must notify the recipient or his or her legal representative or relative. If the transfusion recipient is deceased, the transfusion service or physician must continue the notification process and inform the deceased recipient's legal representative or relative. Reasons for notifying the recipient's relative or legal representative on his or her behalf shall be documented pursuant to § 606.160 of this chapter.

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