DRAFT RECOMMENDATIONS FOR THE QUARANTINE AND DISPOSITION OF POTENTIALLY HBV, HCV OR HTLV-I CONTAMINATED UNITS FROM PRIOR COLLECTIONS FROM REPEAT DONORS WITH REPEATEDLY REACTIVE SCREENING TESTS. (Intended for discussion at the meeting of the BPAC on 12/15/94.)

I. Scope of the Recommendations

A. The FDA recommends excluding from use for transfusion and further manufacture into injectable products previously collected units of Whole Blood, blood components, Source Leukocytes or Source Plasma from any donor who subsequently tests repeatedly reactive by a licensed screening test for HBsAg, and who does not have a negative test result by a licensed confirmatory (neutralization) test for HBsAg on the repeatedly reactive unit.

B. The FDA recommends excluding from use for transfusion and further manufacture into injectable products previously collected units of Whole Blood, blood components, Source Leukocytes or Source Plasma from any donor who subsequently tests repeatedly reactive by a licensed screening test for anti-HCV, and who does not have a negative test result by a licensed supplemental test for anti-HCV on the repeatedly reactive unit.

C. The FDA recommends excluding from use for transfusion previously collected units of Whole Blood and blood components from any donor who subsequently tests anti-HBc repeatedly reactive by a licensed screening test for anti-HBc, and who does not have a negative test result by a second anti-HBc licensed screening test of a different type for anti-HBc on the repeatedly reactive unit.

D. The FDA recommends excluding from use for transfusion previously collected units of Whole Blood and blood components from any donor who subsequently tests anti-HTLV-I repeatedly reactive by a licensed screening test for anti-HTLV-I, and who does not have a negative test result by a second licensed screening test of a different type for anti-HTLV-I on the repeatedly reactive unit.

II. Recommended Procedures

A. Quarantine of Potentially Contaminated Units

Whenever a repeat donor has a repeatedly reactive screening test for HBsAg, anti-HBc, anti-HCV or anti-HTLV-I, blood establishments should promptly, within 72 hours if possible, identify and quarantine within-date blood and blood components in inventory from prior collections, extending back 5 years. If, for the test that is repeatedly reactive, there is a record available of the donor's last negative test results from a licensed screening test, then quarantine of prior collections should only extend back to 12 months before such a test.

In addition, blood establishments should promptly request consignees of such products to immediately quarantine all previously distributed products extending back 5 years or 12 months before the donor's last negative test results from licensed serological tests. FDA is not recommending, in the case of products intended for further manufacturing use, that blood establishments request consignees to quarantine units collected more than six months in the past. FDA is also not recommending that products which have been already pooled or further processed be quarantined. FDA does not intend to evaluate these actions as recalls, provided that the blood establishment adheres to applicable regulations and SOPs.

If additional tests on the repeatedly reactive units are performed within 72 hours and test results provide a basis for release of units as described in C., then quarantine of the previously collected unitsis not necessary.

B. Disposition of Units Placed in Quarantine

For donors who test repeatedly reactive for HBsAg, anti-HCV, anti-HBc, or anti-HTLV-I, additional testing on a sample from the donor's current (repeatedly reactive) collection may permit release from quarantine (see section C. below). If such

testing fails to be performed within 30 days or fails to meet procedures established for release of units from quarantine (see section C.), then the quarantined units should be destroyed or appropriately labeled either as, 1) "biohazard" and "Not for use for transfusion or further manufacturing into injectable products", in the case of products originating from donors who subsequently test repeatedly reactive for HBsAg or anti-HCV, or as, 2) "biohazard" and "Not for use for transfusion", in the case of products originating from donors who subsequently test repeatedly reactive for anti-HBc or anti-HTLV-I.

C. Release of Units from Quarantine

1. FDA recommends that units of blood, blood components, Source Leukocytes and Source Plasma from prior collections of donors who subsequently test HBsAg repeatedly reactive, be considered for release for transfusion or for further manufacture into injectable products, if the donor's current (repeatedly reactive) blood sample is further tested by the appropriate licensed confirmatory (neutralization) test for HBsAg and the results are negative.

2. FDA recommends that units of blood, blood components, Source Leukocytes and Source Plasma from prior collections of donors who subsequently test anti-HCV repeatedly reactive, be considered for release for transfusion or for further manufacture into injectable products, if the donor's current (repeatedly reactive) blood sample is further tested by an appropriate licensed supplemental test for anti-HCV and the results are negative.

3. FDA recommends that units of blood and blood components from prior collections of donors who subsequently test anti-HBc repeatedly reactive, be considered for release for transfusion, if the donor's current (repeatedly reactive) blood sample is further tested by a second licensed screening test of a different type for anti-HBc

and the result is negative.

4. FDA recommends that units of blood and blood components from prior collections of donors who subsequently test anti-HTLV-I repeatedly reactive, be considered for release for transfusion, if the donor's current (repeatedly reactive) blood sample is further tested by a second licensed screening test of a different type for anti-HTLV-I and the result is negative.

5. FDA recommends that units of blood components be considered for release, if the previous collection (that is in quarantine) occurred more than one year prior to the donor's most recent negative screening test (for the marker of concern). See section II.A.

D. Blood establishments should have written procedures to identify prior donations, to quarantine units, to notify consignees, and to perform additional testing if release of units from quarantine will be sought, whenever a repeat donor has a repeatedly reactive test for HBsAg, anti-HCV, anti-HBc or anti-HTLV-I. In addition, the establishment's records should enable tracking of prior donations and their disposition, and records should be kept documenting the quarantine of products, consignee notification, and disposition of products identified as potentially contaminated based on subsequent donor testing.

E. For units previously distributed, consignees should be notified within 30 days of the results of additional testing, if performed, so that consignees may either release products (as described in II.C.), or properly dispose of products (in regard to labeling or destruction as described in IIB.).

F. Units that test repeatedly reactive for HBsAg or anti-HCV using licensed screening assays should not be used for transfusion or for further manufacture into injectable products. Units that test repeatedly reactive for anti-HBc or anti-HTLV-I

should not be used for transfusion.

References

1. Recommendations for the Management of Donors and Units that are Initially Reactive for Hepatitis B Surface Antigen (HBsAg), December 2, 1987.

2. HTLV-I Antibody Testing, November 29, 1988.

3. FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc), September 10, 1991.

4. Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV), August 5, 1993.

5. Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Components, April 23, 1992.

6. Proposed Rule: Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection, Docket No. 91N-0152, June 30, 1993.

7. MMWR: Public Health Service Inter-Agency Guidelines for Screening Donors of Blood, Plasma, Organs, Tissues and Semen for Evidence of Hepatitis B and Hepatitis C, April 19, 1991, Vol.40, No.RR-4.

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