

Recipient Serum Samples (4/6/94)

Date: April 6, 1994

From: Director
Division of Field Investigations (HFC-130)

Subject: Recipient Serum Samples

To: Investigations Branch Directors

Information: Regional Food and Drug Directors
District Directors

21 CFR 606.151(b) states standard operating procedures for compatibility testing shall include the use of fresh recipient serum samples less than 48 hours old for all pretransfusion testing. The Office of Compliance, Center for Biologics Evaluation and Research (CBER), has advised DFI that holding samples more than 48 hours is not, by itself, objectionable.

The 48 hour timeframe was selected in the 1970s. During this period, it was thought that the time limit was needed to assure that "complement" was present to detect clinically significant antibodies in the crossmatch procedure. Following a review of additional information by the Blood Products Advisory Committee, CBER issued a guidance memorandum to the blood banking industry on December 14, 1984 to permit alternative methods for the antiglobulin phase of the crossmatch. The memorandum addressed elements of compatibility procedures that would be equivalent to procedures found in 21 CFR 606.151; however, it did not specify the age of the sample to be used in a crossmatch. Although the regulation is still in place, CBER does not regard it as a serious concern. We anticipate that, through the current retrospective review of the regulations, this requirement will be modified to reflect the current standard in the industry, which is a longer time period.

Establishments must have SOPs setting age specifications for samples to be used in a crossmatch and criteria to assure the identity and integrity of the sample(s). Criteria may include, but are not limited to, testing serum of patients who have been pregnant or transfused within three months and infants.

While there is no upper time limit for use of a sample, we expect that the firms should have established procedures to ensure proper controls over use of older samples. Extended periods of time for holding test samples should be discussed with CBER, if encountered.

For further guidance, contact Mary Ann Tourault, OC/CBER, HFM-655, (301) 594-1191.

Robert C. Fish