Equivalent Methods for Compatibility Testing (12/14/84)

December 14, 1984

FROM: Acting Director, Office of Biologics Research and Review

SUBJECT: Equivalent Methods for Compatibility Testing

TO: All Registered Blood Establishments

Background:

In response to the large public interest generated by several publications which suggested that the antiglobulin crossmatch was unnecessary in many situations, the FDA sponsored a workshop in December 1981 on "The Role of Compatibility Tests." The Blood Products Advisory Committee in attendance at this workshop recommended revising 21 CFR 606.151 to permit alternative methods for the antiglobulin phase of the crossmatch. We are in agreement with this recommendation but proposals to chance the current rules have not yet been published in the Federal Register.

Recognizing both the significant cost savings that the chances proposed by our Advisory Committee would effect, and considering the public awareness of FDA's direction (Garraetv, G., Transfusion: 22, p. 169, 1982), we have informed FDA inspectors that in many situations the "type and screen" procedure is an acceptable alternative to crossmatching.

Equivalent Procedures:

We consider compatibility procedures which include the following elements as equivalent to the procedures prescribed in 21 CFR 606.151 for the purpose of preparing blood for transfusion:

(a) A method of collecting and identifying the blood samples of recipient using donors to ensure positive identification.

(b) The determination of the ABO and Rh groups of the donor and recipient using licensed blood grouping sera or their equivalent.

(c) Antibody detection tests that will demonstrates significant alloantibodies, by the active at 37 C in the serum or plasma of a previously transfused or previously pregnant donor.

(d) The testing of the recipient's serum for unexpected alloantibodies, by the antiglobulin technique or an equally sensitive method that will demonstrate significant

antibodies reactive with the donor's cells at 37 C.

(e) Procedures to expedite transfusions in life-threatening emergencies and, if applicable, procedures for testing blood for neonatal transfusions and autologous transfusions.

You will note that the above requirements permit the substitution of an adequate antibody screening test (d) for the major crossmatch. Such procedures have been very widely applied and, as reflected by the new AABA Standards, have been successful in assuring safe transfusion. We will continue to evaluate questionable crossmatch practices on a case-by-case basis.

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