Computerization of Blood Establishments (9/8/89)

Date: September 8, 1989

From: Director, Center for Biologics Evaluation and Research

Subject: Requirements for Computerization of Blood Establishments

To: All Registered Blood Establishments

I. INTRODUCTION

This memorandum is intended to provide further guidance on the use of computer systems in registered blood establishments as previously addressed in a memorandum dated April 6, 1988.

Computer systems are being employed more frequently in blood establishments, not only for recordkeeping, but for activities intimately involved in processes and procedures integral to the collection, processing, storage and distribution of blood and blood components. When personnel depend on the computer system in making decisions regarding the suitability of donors and the release of blood or blood products for transfusion or further manufacture, the computer system is considered to have "control functions."

Computer systems which perform control functions are subject to current good manufacturing practices, 21 CFR 211 and 606. Computer systems, both hardware and software, employed in the performance of these control functions fall within the meaning of 21 CFR 606.60 (Equipment) and 21 CFR 211.68 (Automatic, mechanical, and 21 CFR 606.160 (Records).

Computer software used for retention of data relating to donor suitability and deferral, blood processing (including testing), component preparation, storage or disposition is subject to all recordkeeping requirements applicable to manual systems as prescribed by 21 CFR 606.160 (Records).

Blood establishments using computer systems in control functions must assure that the computer system performs consistently and as required in meeting all user requirements. Documentation of validation criteria and procedures must be maintained, and computer systems installed or modified after the date of this memorandum should not be incorporated into daily operations without initial acceptance testing and management review. The volume and type of documentation required to validate the computer system will vary according to the nature and extent of the control functions and the degree of reliance placed on the computer system during critical steps in use. Documentation should clearly show that all components of the computer system have been qualified and operate properly before final implementation of the total computer system. For systems that are

currently installed, retrospective review must demonstrate compliance with 21 CFR 606.60 and 21 CFR 606.160. Documentation must also demonstrate that the computer system has been properly challenged and that conversion to and reliance on the system does not contribute to the release of unsuitable blood products.

II. STANDARD OPERATING PROCEDURES

The following items must be incorporated into standard operating procedures and be available for review during establishment inspections of all registered blood establishments:

1. Procedures relating to integration of the computer system into operations.

2. Procedures for reverting to manual procedures when the system is not functioning.

3. Back-up procedures for data storage including frequency and the disaster recovery plan.

4. Procedures for the partial or complete shutdown of the system or its interfaces to ensure the integrity of data and to document proper functioning of the system after restarting.

5. Maintenance procedures for hardware and software.

6. Security procedures to prevent unauthorized entry and physical access to the computer system.

?. Validation protocols followed to independently test and challenge the critical functions and procedures.

8. Procedures for the active review of system functioning and timely correction of errors.

9. Procedures for control of changes in hardware/software.

10. Procedures for initial and continued training of personnel.

III. RECORDKEEPING

Registered blood establishments must maintain records of the outcomes of procedures outlined in III above including identification of personnel involved in performing and reviewing the procedures. These records must be in compliance with 21 CFR 606.160 and available for review at the time of inspection.

IV. ESTABLISHMENT LICENSE APPLICATIONS/AMENDMENTS

Blood establishments are responsible for assuring that the

computer system repeatably and reliably performs as intended. For
LICENSED establishments only, the use of computers in control Functions constituted a change that must be reported to the Director, CBER [2lCFR 601.12 (a)].

The following information should be submitted by licensed establishments in the form of amendments to their establishment license applications. Submissions should be directed to the Director, CBER, through the Division of Product Certification (HFB-240), 8800 Rockville Pike, Bethesda, MD 20892 within 90 days of the date of this memorandum:

1. Identification of the source(s) of the application software used in control functions and the current version(s) in use.

2. A description of the control functions to be performed by the computer system.

V. QUESTIONS AND COMMENTS

Please refer questions concerning licensing to the Division of product Certification, HFB-240, (301) 443-5433. Other questions should be referred to the division of Blood and Blood Products, HFB-400, (301) 496-4396.

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