Computerization in Blood Establishments (4/6/88)

DATE: April 6, 1988

TO: ALL REGISTERED BLOOD ESTABLISHMENTS

SUBJECT: Recommendations for Implementation of Computerization in Blood Establishments

FROM: Director, Center for Biologics Evaluation and Research

The following basic principles are recommended to provide for uniformity and consistency in the use of computers in blood establishments.

Automated or electronic data systems used in blood and plasma establishments should have the capacity to trace the history of every donation forward through final disposition of each component and from each transfusion, infusion or sale backward to the original donor.

Implementation of computerization for data handling between automated devices or for interpretive and control functions is considered a major change in manufacturing methods that required a license amendment for licensed establishments.

Prior to approval all systems will be evaluated for evidence of validation by the establishment that computer programs, especially those dealing with processing, labeling, and distribution of blood and blood components, consistently perform as required and within pre-established limits. In addition, when the establishment has developed its own software de novo or has an agreement that software modification may be performed by the establishment on the vendor's original product, in-depth review will extend to the more specific concerns these activities raise.

Validation procedures for all systems, whether purchased entirely or developed in whole or in part in the establishment, will be reviewed for confidentiality of donor information, security of data, and system documentation, as described in Sections I-III following. Additional scrutiny for software development, both de novo and as modifications to a purchased system, is discussed in Section IV.

I. CONFIDENTIALITY OF DONOR INFORMATION: Each establishment should develop procedures to provide for confidentiality of sensitive medical information about the donor. These procedures should prevent inadvertent release of this information and protect privacy from both external and unauthorized internal inquiries.

II. SECURITY OF DATA: If key elements of the

database are changed, these changes should be traceable as to the time and person making the change so that integrity and reproductibility of data are assured. Persons authorized to make changes should be specifically identified. Periodic audits of stored data should be undertaken to assure that timely retrieval and accurate information reporting are available. Hard copy of stored data should be available within 4 to 6 hours of request by an authorized investigator. Control and use of passwords should be strictly enforced. Consideration should also be given to offsite storage facilities or other backup systems for computer tapes/discs that store information vital to record keeping for the blood center.

III. DOCUMENTATION OF SYSTEM: Documentation should include system diagrams, charts, and descriptions detailing both hardware and software components. The location and means of access to source code, including a letter of agreement from the vendor that permits FDA investigators access to the source code, should be identified in the procedures manual. Software/hardware integration and verification testing (i.e., validation) procedures should be well defined, and all possible stress/load situations listed in the program manual. Any change to the program should be fully documented and validated prior to being implemented, with all validation testing results suitably documented. A recovery plan should be available in case of a disaster. Packaged software should have the same testing requirements, and no system should so on-line until all elements are in place and there is verification that the system produces reliable results. Training manuals, user manuals, and records of personnel training should be available for review.

IV. STANDARDS AND PROCEDURES FOR DEVELOPMENT AND MODIFICATION OF SOFTWARE: Written program development standards should be in place that detail any requirements and/or restrictions to be followed then writing or modifying the computer program. Programs should be identified by name, purpose, version, language and date.

Specifications for software design, the process of defining the software architecture, components, modules, interfaces, test approach and test data for a Software system according to system requirements, must be formally developed and written for each system application. This document is the guide/instruction to those responsible for writing or modifying and maintaining the computer programs and should include specific instructions for revising and documenting updates to the system. All of the

foregoing should be available for review at the time of an authorized FDA inspection.

Questions should be directed to:

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