**Section 490.910 Records**

a) Records shall be maintained concurrently with the performance of each step in the collection, processing, compatibility testing, storage and distribution of each unit of blood or blood component in accordance with FDA standards (21 CFR 606, Subpart I)(1987).

b) Complete records in regard to each specimen examined shall be kept on file in the blood bank for not less than five years. Such records shall contain:

1) Laboratory number or other identification of the specimen;

2) The name or other means of identification of the person from whom the specimen was taken;

3) The name of the licensed physician or other authorized person, clinical laboratory, or blood bank submitting the specimen;

4) The date the specimen was collected and the date the specimen was received in the blood bank;

5) When a specimen is forwarded to another clinical laboratory or blood bank for tests, the name, the date when the specimen was forwarded to such laboratory or blood bank, the date it was tested, and the date the report of the findings of the test was received from such laboratory or blood bank;

6) In case the specimen is an unsatisfactory specimen, the condition of the specimen when received;

7) The types and numbers of tests performed annually; and

8) The result of the test conducted by the blood bank, the method used, the signature of the examiner.