**Section 490.520 Preventive Maintenance of Equipment and Instruments**

a) Preventative Maintenance Program

1) The blood bank must establish a written preventive maintenance program for each piece of equipment. The program shall be documented and implemented on a regularly scheduled basis (i.e. at least semi-annually). It shall provide for instrument function verification and equipment maintenance.

2) The preventive maintenance programs shall at minimum coincide with the manufacturer's recommendations.

b) Service Contract

1) A service contract from an outside source for preventive maintenance is acceptable, provided there is a description of the services to be performed for each piece of equipment or instrument and a statement of the frequency of maintenance to be performed.

2) A service contract does not negate the blood bank's responsibility to perform other routine maintenance as required by the written program.

3) The blood bank must maintain records of preventive maintenance whether performed by the blood bank staff or by an outside source.

c) Specific Laboratory Equipment

1) Automatic dilutors and samplers, except those checked by use of a calibrator or reference material included in each run, shall be checked for accuracy and reproducibility at least once per month.

2) A serum/cell calibration shall be performed on a serofuge when first put into operation and after any adjustments or repairs which affect the speed, or balance during the operation of the instrument. Accuracy of the timer and RPM shall be checked at least quarterly.

3) Volumetric glassware (pipets, flasks) that is not designated "class A" by the manufacturer, shall be calibrated to confirm its designated volume.

4) Thermometer readings for temperature controlled spaces and instruments shall be recorded each day of use.

5) All thermometers in the blood bank shall be checked against a reference thermometer (certified by the National Bureau of Standards or guaranteed by the manufacturer to meet the National Bureau of Standards criteria) before being placed into use and annually thereafter.

6) Donor scales shall be checked for accuracy each day of use.

7) Glassware shall be free from scratches and cloudiness, and graduations shall be legible. "To contain" and "to deliver" pipettes shall be separated.

8) Analytical balances shall be checked for accuracy at least annually, and accuracy of weights verified by using "Class A Weights".