**Section 450.520 Preventive Maintenance of Equipment and Instruments**

a) Preventative maintenance program

1) The laboratory must establish a written preventive maintenance program for each piece of equipment. The program shall be documented and implemented on a regularly scheduled basis. 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 instrument or each piece of equipment and a statement of the frequency of maintenance to be performed.

2) A service contract does not negate the laboratory's responsibility to perform other routine maintenance as may be required.

3) The laboratory must maintain records of preventive maintenance whether performed by the laboratory 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 major adjustments or repairs. 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) Cuvettes shall be free of scratches and suitable to the procedure in which they are used. If applicable, the cuvettes should be matched.

5) Specific requirements for checking spectrophotometers and radioactive counting equipment are included in Subpart K.

6) Thermometer readings for temperature controlled spaces and instruments shall be recorded each day of use. Tolerance limits shall be established.

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

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

9) Analytical balances shall be checked for accuracy at least annually and accuracy of weights verified by using 'Class A' weights.

(Source: Amended at 13 Ill. Reg. 11573, effective July 1, 1989)