**Section 450.1140 Procedure Manuals**

a) Current procedure manual(s) prepared by each laboratory shall be available for use by technical personnel. Manufacturer's manuals and textbooks may be used as supplements to the laboratory manual, but not in lieu thereof.

b) Each procedure manual shall contain a table of contents reflecting the name of the test; methodology used; annual review by the director; date and type of change in methodology, instrumentation, reagents, etc., which are approved by the director with cross reference to the actual change in that procedure. Each procedure shall use the headings below and include, where applicable, all items listed. The following format is recommended.

1) Principle of the test.

Include a brief statement concerning the type of reaction(s) involved.

2) Specimen.

A) State the conditions for patient preparation.

B) Specify the type of sample with respect to volume of sample required, anticoagulants, preservatives, stability, and requirements for storage.

C) State the criteria for an unacceptable sample.

D) Specify handling conditions with respect to timing, transport or storage conditions, and special equipment.

E) State the criteria for proper specimen identification.

3) Reagent preparation.

A) List specific reagents used in the procedure.

B) State the directions for preparation and labeling of each reagent to include the initials of the person who prepared the material, contents, concentration, lot number, date of preparation, expiration date, and storage requirement.

C) For coagulation reagents, record the time of reconstitution and initial.

4) Procedure calibration

A) Give detailed stepwise instructions including dilutions of working standards (calibrators). List standards used, grade of purity required and storage requirements.

B) State specifications for photometric readings (%T, absorbance, etc.).

C) Where calibration graphs are used, the type shall be specified.

D) Specify acceptable tolerances for standards and corrective actions to be taken if results are outside the tolerance limits.

5) Procedure.

A) Write detailed instructions in a stepwise manner. A flow chart may be used as an adjunct.

B) Specify the following for photometric measurements.

i) Type of instrument.

ii) Wavelength.

iii) Cuvette size.

iv) Solution used as a blank.

v) Range of linearity.

vi) How the raw data are read (%T, absorbance, etc.).

vii) Stability of the final solution.

C) Clearly indicate safety hazards.

6) Calculations.

A) Give stepwise instructions for calculations.

B) Give the equation.

C) Give a precise example.

D) Describe the common variations in calculations.

7) Quality Control.

A) State the reference materials to be used.

B) Give instructions for preparation of reference materials.

C) State the minimum frequency with which reference materials are to be run.

D) State how action limits for reference materials are to be established.

E) State the corrective actions to be taken when action limits are exceeded.

8) Reporting results.

A) State expected ranges where appropriate.

B) Give information about methodology which may be necessary for interpretation of results.

C) Give guidelines as to acceptable reporting format and units as applicable.

D) A system for handling critical values shall be available.

E) State and laboratory confirmed upper and lower limits of linearity and/or detection limits for the procedure to insure that reported results are within these limits.

9) Procedural notes.

A) List possible sources of error.

B) Describe the plan for an alternate means of specimen handling or analysis in the event the procedure should fail.

10) References.

Document the source(s) of information used in the procedure.

11) Utilization of product package inserts. Include a system to assure that package inserts are current with and applicable to the kits or reagents actually in use. Package inserts may not be used as part of the procedure manual unless they comply with all of the provisions enumerated under this Section.

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