10A NCAC 14E .0309 is proposed for amendment as follows:

10A NCAC 14E .0309  LABORATORY SERVICES

(a) Each clinic shall have the capability to provide or obtain laboratory tests required in connection with the procedure to be performed.

(b) The governing authority shall establish written policies requiring examination by a pathologist of all surgical specimens except for those types of specimens which the governing authority has determined do not require examination.

(c) Pre-operative Tests. As a minimum, there shall be performed for each patient the following laboratory tests which must be recorded. Each patient shall have the following performed and a record of the results placed in the patient's medical record prior to the abortion:

   (1) Pregnancy testing, except when a positive diagnosis of pregnancy has been established by ultrasound;

   (2) Anemia testing (hemoglobin or hematocrit); and

   (3) Rh factor testing.

(d) Blood and Blood Products. Those patients requiring the administration of blood shall be transferred immediately to a local hospital having blood bank facilities.

(e) The facility shall maintain a manual in a location accessible by employees, that includes the procedures, instructions, and manufacturer’s instructions for each test procedure performed, including:

   (1) Sources of reagents, standard and calibration procedures, and quality control procedures;

   and

   (2) Information concerning the basis for the listed "normal" ranges.

(f) The facility shall perform and document, at least quarterly, calibration of equipment and validation of test results.

History Note: Authority G.S. 14-45.1(a); G.S.90-21.83; 143B-10; S.L.2013-366 s.4(c);

Eff. February 1, 1976;

Readopted Eff. December 19, 1977;

Amended Eff. April 1, 2015; July 1, 1994; December 1, 1989; October 28, 1981.