

1 10A NCAC 13M .0101 is proposed for amendment as follows:
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3 **SUBCHAPTER 13M – MAMMOGRAM AND PAP SMEAR CERTIFICATION**
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5 **SECTION .0100 – PAP SMEAR CERTIFICATION**
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7 **10A NCAC 13M.0101 STATE CERTIFICATION FOR LABORATORIES CONDUCTING PAP SMEARS**
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9 (a) All laboratories evaluating Pap smears shall be state certified by the Division of Health Service Regulation,
10 Department of Health and Human Services, in accordance with this Rule.

11 (b) To be state certified, all laboratories shall be licensed under the Federal Clinical Laboratory Improvement Act as
12 amended or certified by the Centers for Medicare and Medicaid Services for the specialty of cytology.

13 (c) To be state certified, laboratories shall perform Pap smear examinations only on specimens submitted by a health
14 care provider whose scope of practice includes the function of Pap smears.

15 (d) An application for state certification shall be submitted to the Division of Health Service Regulation listing the
16 name and location of the laboratory requesting certification, the name of the laboratory director and evidence that the
17 laboratory meets the requirements listed in Paragraphs (b) and (c) of this Rule. Laboratories will be notified in writing
18 within 45 days of receipt of the application that they have been certified, or if certification has been denied, of the
19 reasons for denial.

20 (e) State certification must be renewed by a facility when licensing or certification renewal is required by the program
21 that established state certification eligibility pursuant to Paragraph (b) of this Rule.

22 (f) If a laboratory's license or certification for one of these programs is suspended or revoked, the laboratory director
23 shall immediately notify the Division of Health Service Regulation and the laboratory's state certification under this
24 Rule shall be revoked. The laboratory may apply for recertification when it can provide evidence that it meets the
25 requirements listed in Paragraphs (a) – (e) of this Rule.

26 (g) Appeals of the Division's decision regarding state certification shall be in accordance with the Administrative
27 Procedures Act, G.S. 150B.
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29 *History Note: Authority G.S. 143B-165;*

30 *Temporary Adoption Eff. October 11, 1991 For a Period of 141 Days to Expire on February 29,*
31 *1992;*

32 *Eff. March 1, 1992;*

33 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20,*
34 *~~2015-2015;~~*

35 *Repealed Eff. October 1, 2026.*