

1 10A NCAC 13M .0201 is proposed for readoption as follows:
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3 **SECTION .0200 – MAMMOGRAPHY CERTIFICATION**
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5 **10A NCAC 13M .0201 STATE CERTIFICATION FOR SCREENING OF MAMMOGRAPHY SERVICES**

6 (a) All facilities performing screening mammograms shall be certified by the Division of Health Service Regulation,
7 Department of Health and Human Services in accordance with the Rule.

8 (b) To be state certified, all equipment used in the performance of screening mammography shall be dedicated to such
9 use by manufacturer’s design. Each piece of mammography X-ray equipment, whether located in a fixed or mobile
10 facility, shall be maintained in a safe operating condition and shall be registered and used in accordance with the Rules
11 in 15A NCAC 11.

12 (c) To be state certified, all facilities shall be certified by the Centers for Medicare and Medicaid Services or shall be
13 accredited by the American College of Radiology for the performance of mammography screening.

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

18 (e) State certification must be renewed by a facility certification or accreditation renewal is required by the program
19 that established state certification eligibility pursuant to Paragraph (c) of this Rule.

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

24 (g) The North Carolina Medical Care Commission delegates the authority to grant waivers of this Rule to the Division
25 of Health Service Regulation. The Commission, however, shall review all waivers granted at its next regularly
26 scheduled meeting and shall make any revisions to waivers deemed necessary at that time.

27 (h) In order to be granted a waiver of this Rule, a facility shall make a request for a waiver in writing to the Division
28 of Health Service Regulation providing the following:

- 29 (1) justification that the rule should not be applied as written, because strict application would cause
30 undue hardship;
- 31 (2) justification that adequate standards assuring early detection of breast cancer and affording
32 protection of health and safety exist and will be met in lieu of the exact requirements;
- 33 (3) justification that the purpose of this Rule is met through equivalent standards affording equivalent
34 protection of health and safety;
- 35 (4) information on the number of screening mammograms performed monthly for the previous six
36 months;

1 (5) information proving that there is no state certified facility nearby by identifying the nearest state
2 certified facility and providing information regarding the accessibility of mobile units in the area;
3 and

4 (6) a plan for meeting standards necessary for certification, including the time required to meet
5 standards.

6 (i) The Division of Health Service Regulation may grant a waiver to the extent that the factors listed in Paragraph (h)
7 of this Rule are satisfied.

8 (j) Appeals of the Division's decisions regarding state certification shall be in accordance with the Administrative
9 Procedures Act, G.S. 150B.

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11 *History Note: Authority G.S. 143B-165;*

12 *Temporary Adoption Eff. October 11, 1991 For a Period of 141 Days to Expire on February 29,*
13 *1992;*

14 *Eff. March 1, 1992;*

15 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. Jule 20,*
16 *2015-2015;*

17 *Pursuant to G.S. 150B-21.3A, rule is necessary Eff. June 25, 2025;*

18 *Readopted Eff. October 1, 2026.*