State of Iowa Authorization
Notification of State Mammography Rules

Most of the rules in the Iowa Administrative Code 641 – Chapter 41.6 are exactly the same as the Mammography Quality Standards Act (MQSA) regulations. However, there are several Iowa Administrative Code rules that are more stringent than MQSA. A link to the Iowa Administrative Code rules can be found at https://www.legis.iowa.gov/law/administrativeRules/chapters?agency=641&pubDate=02-28-2018

All mammography facilities providing mammography services within Iowa must comply with these rules in addition to the MQSA regulations.

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1. IAC 641-Chapter 41.6(2)*a*(1)
   Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

2. IAC 641-Chapter 38.8(1)*a*
   Each registrant shall, at the time of registration and the anniversary date thereafter, as long as the registrant owns the radiation machine, remit to the agency a nonrefundable fee sufficient to defray the cost of registering the equipment with the department. All fees shall be paid annually in the form of a check or money order made payable to the Iowa Department of Public Health. The fees to be paid shall be in the amount computed by the following schedule:

Type of X-ray machine	Fee per tube	Maximum fee
Medical	$51	$1500

3. IAC 641-Chapter 38.8(1)*e*
   All mammography facilities providing services in Iowa must submit a $50 annual authorization certification fee.

4. IAC 641-Chapter 41.6(2)*b* and *q*
   Facilities must be authorized by the State of Iowa to perform mammography services in Iowa. This is in addition to the accreditation and certification required by MQSA and applies to both fixed and mobile mammography units.

5. IAC 641-Chapter 41.6(2)*i*
   Soft copy review workstation requirements.
   (1) Soft copy review workstations used for final interpretation of mammogram images must be a configuration of two monitors that meet one of the following criteria:
      1. Have 5 megapixel resolution; or
      2. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.
   (2) The workstation must have a quality control program substantially the same as that outlined by the image receptor manufacturer's quality control manual or that outlined by the image receptor manufacturer's designated soft copy review workstation quality control manual.

6. IAC 641-Chapter 41.6(3)*a*(1)1
   All radiologists interpreting mammograms shall be licensed to practice medicine in Iowa.

7. IAC 641-Chapter 41.6(3) *a*(1)5
   Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least 8 hours of Category 1 continuing medical education credits in the new mammographic modality or at least 8 hours of training in the new mammographic modality provided by a vendor manufacturing the new mammographic modality equipment. An interpreting physician previously qualified to interpret a new mammographic modality in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa new mammographic modality interpretation.

8. IAC 641-Chapter 41.6(3) *a*(2)4
   Continuing qualifications (15 CME in previous 36 months and 960 mammography interpretations in previous 24 months) must be met at all times when the interpreting physician is interpreting mammography.

9. IAC 641-Chapter 41.6(3) *a*(4)1 second bullet
   Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed **to** resubmit for requalification following a 90-day waiting period.

10. IAC 641-Chapter 41.6(3)*b*(1)1
    Radiologic Technologists performing mammography must hold a valid Iowa Permit to Practice.

11. IAC 641-Chapter 41.6(3)*b*(3)4 and IAC 641-Chapter 41.6(3)*b*(4)3
    Continuing qualifications (15 CEU's in previous 36 months and 200 mammogram exams in previous 24 months) must be met at all times when the radiologic technologist is performing mammography exams.

12. IAC 641-Chapter 41.6(3)*b*(3)5
    Radiologic technologists may use CEU's obtained through presenting or training for only 50% (7.5) of the required continuing education requirement.

13. IAC 641-Chapter 41.6(3)*b*(5)
    Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

14. IAC 641-Chapter 41.6(3)*c*(1)1
    Medical Physicists must be approved by the State of Iowa to provide services in Iowa.

15. IAC 641-Chapter 41.6(4)*b*
    Mammography reports must include the following information (in addition to the MQSA requirements):
    - The date of the interpretation.
    - A description of the procedure performed.
    - Name of the referring physician or other physician identified by the patient to receive the written report.
    - A separate and distinct section entitled "Assessment"
    - Information on a patient's breast density, as categorized by an interpreting physician at the facility based on standards as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening, including the breast imaging reporting and data system of the American College of Radiology.

16. IAC 641-Chapter 41.6(5)*h*(2)
    Repeat analysis must be performed every 250 patients. If a facility performs more than 250 patients per week, weekly repeat analysis is acceptable.

17. IAC 641-Chapter 41.6(3)*i*(3)
    The reviewing physician must sign the medical audit.

18. IAC 641-Chapter 41.6(7)*a*
    Safety standards must be in place and maintained for the mammography unit.

19. IAC 641-Chapter 41.6(7)*b*
    Equipment operators must be monitored for radiation exposure in accordance with IAC 641 – 40.37.

20. IAC 641-Chapter 41.6(7)*e*
    Records of all inspections, reports, and consultations (MP surveys) shall be maintained for 7 years.