State of Iowa Authorization
Notification of Iowa Mammography Rules

Most of the rules in the Iowa Administrative Code 641 – Chapter 41.6 are 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 here.

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	Fee per tube	Maximum
Medical	$120	$3000

3. IAC 641-Chapter 38.8(1)e
   All mammography facilities providing services in Iowa must submit a $150 annual authorization certification fee.

4. IAC 641-Chapter 41.6(2)b and f
   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
   Review workstation (RWS) requirements.
   (1) RWS used for final interpretation of mammogram images must meet 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 mammography unit manufacturer's quality control manual, that outlined by the RWS monitor manufacturer's quality control manual or the quality control program outlined by an FDA-approved accrediting body.

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 training in the new mammographic modality.

8. IAC 641-Chapter 41.6(3)a(2)4
   A current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

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)
    Radiologic Technologists performing mammography must hold a valid Iowa Permit to Practice.

11. IAC 641-Chapter 41.6(3)b(3)4
    An Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

12. IAC 641-Chapter 41.6(3)b(3)5
    Radiologic technologists may use CEU's obtained through presenting or as a trainer 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(4)d(3)

Communication of results to the patient (in addition to the MQSA requirements):

- The breast density information as designated in the report pursuant to 41.6(4)*"b"*(10) shall be included in the patient lay letter with a reference to a department-accepted site or document where the patient can obtain more information about breast density. For patients categorized as having heterogeneously dense breasts or extremely dense breasts, or an equivalent determination by another nationally recognized density gradient system, the notification to the patient shall include evidence-based information on dense breast tissue, the increased risk associated with dense breast tissue, and the effects of dense breast tissue on screening mammography and shall be stated in language appropriate for the facility's patient population.

17. IAC 641-Chapter 41.6(5)h(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 inspection reports and medical physicist surveys shall be maintained for 7 years.

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1. Has any state or other jurisdiction of the United States or any other nation ever limited, restricted, warned, censured, placed on probation, suspended, revoked, or otherwise disciplined a professional license, permit, registration, or certification issued to you or the organization? ☐ Yes ☐ No
   If yes, include the date, location, reason, and resolution.

2. Have there ever been judgments or settlements paid on your behalf or on the organization's behalf as a result of a professional liability case? ☐ Yes ☐ No
   If yes, include the date, location, reason, and resolution.

3. Have you or the organization ever had a license, permit, registration, or certification denied, suspended, revoked, or otherwise disciplined by a certification body? ☐ Yes ☐ No
   If yes, provide a description of the circumstances.

Terms and Conditions

I am authorized to complete this document on behalf of the organization. As representative of the organization, I hereby certify and declare under penalty of perjury that the information I provided in this document, including any attachments, is true and correct. As said representative of the organization, I am responsible for the accuracy of the information provided regardless of who completes and submits the application. I understand that providing false and misleading information in or concerning this application may be cause for disciplinary action, denial, revocation, and/or criminal prosecution. I also understand that a representative of the organization is responsible to update information submitted herewith if the response or the information changes.

In signing this document, the organization agrees to any reasonable inquiry that may be necessary to verify or clarify the information provided on or in conjunction with this application.

I understand this information is a public record in accordance with Iowa Code chapter 22 and that application information is public information, subject to the exceptions contained in Iowa law.

I have read the Administrative Rules governing this license, permit, registration, or certification and will make employees aware as required and will comply with those provisions.

Signature:			
Facility Name:			
MQSA Facility ID #		**Date:**	