

641—41.10(136C) Quality assurance for mammography. Mammography facilities shall comply with the quality assurance requirements of 21 CFR 900.12(d), 21 CFR 900.12(e), 21 CFR 900.12(f) and the requirements of this chapter.

41.10(1) Mammography facilities shall comply with the general quality assurance requirements of 21 CFR 900.12(d).

a. Mammography facilities shall comply with the requirements of responsible individuals found in 21 CFR 900.12(d)(1).

b. Mammography facilities shall comply with the quality assurance records requirements of 21 CFR 900.12(d)(2).

c. Mammography facilities shall comply with the equipment quality assurance requirements of 21 CFR 900.12(e).

d. Mammography facilities shall comply with the quality control test requirements of 21 CFR 900.12(e)(1) through 21 CFR 900.12(e)(6).

e. Mammography facilities shall comply with the mobile unit requirements of 21 CFR 900.12(e)(7).

f. Mammography facilities shall comply with the use of test results requirements of 21 CFR 900.12(e)(8).

g. Mammography facilities shall comply with the survey requirements of 21 CFR 900.12(e)(9).

h. Mammography facilities shall comply with the mammography equipment evaluation requirements of 21 CFR 900.12(e)(10).

i. Mammography facilities shall comply with the facility cleanliness requirements of 21 CFR 900.12(e)(11).

j. Mammography facilities shall comply with the calibration of air kerma measuring instrument requirements of 21 CFR 900.12(e)(12).

k. Mammography facilities shall comply with the infection control requirements of 21 CFR 900.12(e)(13).

l. Mammography facilities shall comply with the mammography medical outcomes audit quality assurance requirements of 21 CFR 900.12(f).

m. Mammography facilities shall comply with the mammographic procedure and techniques for mammography of patients with breast implant requirements of 21 CFR 900.12(g).

n. Mammography facilities shall comply with the consumer compliant mechanism requirements of 21 CFR 900.12(h).

o. Mammography facilities shall comply with the clinical image quality requirements of 21 CFR 900.12(i).

p. Mammography facilities shall comply with the mammography review and patient and referring provider notification requirements of 21 CFR 900.12(j).

41.10(2) Reserved.

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