

641—41.9(136C) Contents and terminology for mammography. Mammography facilities shall comply with the contents and terminology requirements of 21 CFR 900.12(c)(1) and this chapter.

41.9(1) A separate and distinct section entitled “Assessment” with the appropriate assessment term or an approved equivalent shall be included.

41.9(2) The breast density information as designated in the report pursuant to this chapter 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.

41.9(3) Mammography facilities shall comply with the requirements for the communication of mammography results to patients found in 21 CFR 900.12(c)(2).

41.9(4) Mammography facilities shall comply with the requirements for the communication of mammography results to health care providers found in 21 CFR 900.12(c)(3).

41.9(5) Mammography facilities shall comply with the recordkeeping requirements of 21 CFR 900.12(c)(4) and 641—subrule 37.12(2). Facilities performing mammography shall maintain mammography records for a minimum of seven years.

41.9(6) Mammography facilities shall comply with the mammographic image identification requirements of 21 CFR 900.12(c)(5).

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