**Section 370.50 Requirements for Certification**

a) Except as otherwise provided in subsection (b)(1)(C) and Section 370.40, a certificate issued by the Agency is required for lawful operation of all mammography facilities subject to the provisions of this Part. Facilities performing mammography shall meet the requirements of Sections 370.70, 370.80, 370.90, 370.100, 370.110, 370.120 and 370.130 and be accredited by an FDA-approved accreditation body. Each mammography unit shall be accredited by or have an application pending for accreditation with an FDA-approved accrediting body.

AGENCY NOTE: Currently, the only FDA-approved accrediting body in Illinois is the American College of Radiology.

AGENCY NOTE: Except for provisional certificates and interim notices, the term of certificates issued under this Section shall be for 3 years.

b) Application.

1) Certificates.

A) In order to qualify for a certificate, a facility shall apply to an accreditation body.

B) Following the Agency's receipt of the accreditation body's decision to accredit a facility, the Agency may issue a certificate to the facility, or renew an existing certificate, if the Agency determines that the facility has satisfied the requirements for certification or recertification.

C) An interim notice authorizes the facility to perform mammography until the facility receives its certificate but in no case for more than 45 days. No more than one interim notice may be issued to a facility per application for certification. The Agency may issue an interim notice of mammography certification by facsimile to a facility if a delay is anticipated in providing a certificate to the facility under one or more of the following circumstances:

i) The Agency has been notified by an accreditation body that the facility meets the requirements for a provisional or provisional reinstatement certificate and delivery of the certificate may take more than 24 hours;

ii) The Agency has been notified by an accreditation body that the facility has completed accreditation or reaccreditation and delivery of the certificate to the facility may take more than 24 hours; or

iii) The Agency has been notified by an accreditation body that the facility has timely submitted an application for accreditation or reaccreditation but the completion of the accreditation process may extend beyond the expiration date of a facility's existing certificate through no fault of the facility.

2) Provisional certificates. A new facility is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process.

A) To receive a provisional certificate, a facility shall apply and submit the required information to an FDA-approved accreditation body.

B) Following the Agency's receipt of the accreditation body's decision that a facility has submitted the required information, the Agency may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements for provisional certification. A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90 day extension of the provisional certificate.

C) In the event the facility is denied accreditation by the accrediting body with time remaining on the provisional certificate, the provisional certificate expires immediately with the denial and the facility must stop performing mammography.

3) Extension of provisional certificate.

A) To apply for a 90 day extension to a provisional certificate, a facility shall submit to its accreditation body a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

B) Following the Agency's receipt of the accreditation body's decision that a facility has submitted the required information, the Agency may issue a 90 day extension of the provisional certificate to the facility upon determination that the facility has satisfied the requirements for the 90 day extension.

C) There can be no renewal of a provisional certificate beyond the 90-day extension.

c) Reinstatement policy. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA or the Agency, or that has had its certificate suspended or revoked by FDA or the Agency, may apply for reinstatement. If reinstated, the facility will be eligible for a provisional certificate.

1) Unless prohibited from reinstatement under subsection (c)(4), a facility applying for reinstatement shall:

A) Contact an FDA-approved accreditation body to determine the requirements for reapplication for accreditation;

B) Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

i) Name and address of the facility under which it was previously provisionally certified or certified;

ii) Name of previous owner/lessor;

iii) Facility identification number assigned to the facility under its previous certification; and

iv) Expiration date of the most recent provisional certificate or certificate; and

C) Justify application for reinstatement of accreditation by submitting to the accreditation body a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse, denial of renewal or revocation of its certificate.

2) The Agency may issue a provisional certificate to a previously certified facility:

A) Following the Agency's receipt of the accreditation body's decision that a facility has adequately corrected, or is in the process of correcting, pertinent deficiencies at the facility; and

B) The Agency determines that the facility has taken sufficient corrective action since the lapse, denial of renewal or revocation of its previous certificate.

3) After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

4) If a facility's certificate was revoked on the basis of an act described in Section 370.160, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years after the date of revocation.

d) Appeals of adverse accreditation or reaccreditation decisions. The appeals procedures described in this subsection (d) are available only for adverse accreditation or reaccreditation decisions that preclude certification or recertification by the Agency.

1) Upon learning that a facility has failed to become accredited or reaccredited, the Agency will notify the facility that the Agency is unable to certify that facility without proof of accreditation.

2) A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body. A facility shall avail itself of the accreditation body's appeal process before appealing that decision to the FDA.

3) In the event that a facility, after availing itself of the accreditation body's appeal process, receives an adverse accreditation or reaccreditation decision, the facility may appeal that decision to the FDA. In order to appeal, the facility shall send a request for reconsideration to the FDA

(Source: Amended at 36 Ill. Reg. 17392, effective November 30, 2012)