POLICY AND STANDARD OPERATING PROCEDURES WHEN MAMMOGRAPHY FACILITIES IN STATES THAT HAVE ACCREDITATION BODIES INTEND TO CHANGE ACCREDITATION BODIES

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Mammography Standards Branch
Division of Mammography Quality and Radiation Programs
Office of Health and Industry Programs

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Food and Drug Administration
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POLICY AND STANDARD OPERATING PROCEDURES WHEN MAMMOGRAPHY FACILITIES IN STATES THAT HAVE ACCREDITATION BODIES INTEND TO CHANGE ACCREDITATION BODIES

Background:

In those states that have approved accreditation bodies, facilities may choose to be accredited either by the American College of Radiology or by the state accreditation body (accreditation body). In some instances, facilities accredited by one accreditation body have chosen to change to the other (i.e., new) accreditation body. This occurs most commonly at the time of renewal of accreditation, but may occur prior to that time, and may in some cases occur subsequent to a denial or expiration of accreditation. The latter two cases are in some ways the simplest, but also create their own set of special requirements. These will be dealt with separately later in this document.

To facilitate notification of intent to change accreditation bodies under the FDA data base system, i.e., the Certification and Accreditation Support System (CASS), FDA has requested that new accreditation bodies notify FDA and the prior accreditation body by e-mail whenever they learn that a facility intends to change accreditation bodies. When the new accreditation body notifies FDA that a facility intends to change accreditation bodies, FDA can manually change the facility's accreditation body affiliation in CASS, which will allow the new body to update the facility record and prevent the old body from doing so. There have been problems when a prior accreditation body receives such notice from a facility, and then changes the status of the facility to withdrawn. This does not create a problem as long as FDA changes the facility affiliation before the accreditation body changes the status to withdrawn. The new accreditation body will process an accreditation application from the facility, and if it passes, FDA will receive a record to that effect, and issue a new certificate. If the facility fails and is denied accreditation, FDA will receive a record to that effect, recall the facilities certificate, if not expired, and the facility will have to go through reinstatement to again apply for accreditation. However, if the prior accreditation body changes the facility status to withdrawn before the facility affiliation is changed, the CASS record will show the facility as withdrawn, and the facility's certificate will be inadvertently recalled. The notification procedure below is intended to preclude such problems.

Database issues:

The availability of two accreditation bodies creates special database needs that are exacerbated when facilities change accreditation bodies. It is necessary that our database be affiliated with only one of the two accreditation bodies, permitting only it to enter data for any given facility, and that the affiliated accreditation body be the accreditation body that accredits the facility. However, when a facility decides to change accreditation bodies, and applies to the new accreditation body for reaccreditation it is necessary for the database affiliation to be changed to accept data for the facility from the new accreditation body and preclude acceptance of data from the prior accreditation body.

The number of facilities that change accreditation bodies is small compared with the total of mammography facilities in the United States. Consequently it was determined that notification of the intent of facilities to change accreditation bodies would not be automated in CASS since it would be an exceptional case rather than a routine procedure.

Notification procedure for accreditation bodies when informed of a facility's intent to change accreditation bodies:

FDA has determined, in consultation with the accreditation bodies, that the following procedures should be followed to process a facility's request to change accreditation bodies.

1. When an accreditation body receives notice of a facility's intent to change its accreditation from it to another body, it should make no change in the facility status until it has been notified that the new body has received and accepted an application for accreditation from the facility.

2. When an accreditation body receives notice of a facility's intent to change its accreditation to it but does not receive an acceptable application for accreditation, the accreditation body should make no notification and make no changes to its database.

3. Upon receipt and acceptance of an application for accreditation from a facility intending to change accreditation bodies, the new accreditation body should notify both FDA[1] and the prior accreditation body by e-mail.

4. Upon receipt of this notification, FDA should switch the facility's affiliation in CASS so that CASS will accept data for the facility from the new body, and not accept data from the prior body.

5. To preclude FDA from receiving a status change report before the facility affiliation is manually changed, both accreditation bodies should wait two business days after the notification of acceptance of an application before transmitting updated records for the facility to FDA. The prior body need not transmit any further record for the facility. The new body should only transmit a record when there is a change in the facility's status.

Change of accreditation body subsequent to denial or expiration of accreditation:

A facility that has been denied accreditation, or has allowed its accreditation to lapse, should be reinstated before it can resume performing mammography. Reinstatement involves submission and completion of a corrective action plan to the satisfaction of the accreditation body, and in some cases the FDA. The requirements should be no less stringent for a facility that decides to change accreditation bodies to seek reinstatement. Facilities should be requested to provide a complete accreditation and certification history when applying for accreditation, and this becomes particularly cogent when a facility seeks reinstatement with a new accreditation body. It is essential that the new body be fully aware of the issues that made reinstatement necessary.

[1] At present, such e-mail messages should be addressed to Stella Wei, weis@cdrh.fda.gov

In such cases, in addition to the accreditation history provided by the facility, the new accreditation body should contact the prior accreditation body by e-mail, with a copy to the FDA accreditation liaison officer, and request a complete history of the facility's prior accreditation or attempts at accreditation. The prior accreditation body should provide such history, including pertinent information about any failure or revocation of accreditation.

The new accreditation body, in consultation with FDA through the accreditation body liaison officer, when appropriate, should then request a corrective action plan from the facility in accordance with the accreditation body's policies.

Accreditation body of record:

When switching accreditation bodies, which accreditation body is the facility's accreditation body of record may be ambiguous if the change is not subsequent to a denial or expiration of accreditation. The facility's certificate will usually remain in effect until it expires, is replaced by a new certificate, or accreditation is denied. That certificate is predicated upon accreditation by the prior accreditation body. Unless such accreditation were revoked for cause, FDA would not usually make a determination that a facility's certificate were no longer in effect.

However, once the CASS affiliation has been changed, only the new accreditation body is able to change facility status information in CASS. It is therefore incumbent on the new accreditation body to ensure that the facility is able to operate as long as it should be able to do so under FDA and accreditation body policy. This includes submitting or having the facility submit a request for an interim notice when necessary, and determining when such a notice is appropriate in accordance with the FDA's and the accreditation body's policy. When a facility has not completed renewal of accreditation before its certificate has expired, and the issuance of an interim notice is not appropriate, the new accreditation body should make a determination concerning reinstatement of the facility in accordance with its policies.