

---

## Diagnostic Services – Department of Radiology – Diagnostic Division

---

**SUBJECT/TITLE:** Management of Unresolved Serious Complaints in Breast Imaging

**PURPOSE:** The Breast Imaging division of the Department of Radiology has obtained accreditation in breast imaging from the American College of Radiology (ACR). This policy assures the unresolved serious complaints are reported as required by the ACR and the Mammography Quality Standards Act (MQSA 0 of 1992).

**DEFINITIONS:** A serious complaint is defined by the FDA as a serious adverse event, which means an event that significantly compromises clinical outcomes or one for which a facility fails to take appropriate corrective action in a timely manner.

**POLICY:**

1. Any complaint received regarding mammography services will be treated in accordance with the University of Iowa Hospitals and Clinics Policy Responding to Patient Complaints and Grievance, RI-PR-05.12.
2. If attempts to resolve complaints in consultation with the Patient Representative Program are unsuccessful, the unresolved serious complaints regarding mammography services will be reported to the ACR in accordance with the MSQA of 1992.

**PROCEDURE:**

ACR guidelines for submission are as follows:

1. All unresolved serious consumer complaints must be submitted to the ACR in writing.
2. The complaint should include the consumer's name, address, telephone number, the and location of the ACR accredited mammography facility where the examination was performed, a description of the complaint and the consumer's signature (if reported by the consumer).
3. The complaint should also include copies of any supporting documentation that would be helpful in addressing this complaint.
4. The complaint may be either faxed, e-mailed or mailed to the following address:

Assistant Director, breast Imaging Accreditation Programs  
American College of Radiology  
1891 Preston White Drive  
Reston, VA 20191-4397  
Tel: (800) 227-6440  
Fax: (703) 648-9176  
[Mamm-accred@acr.org](mailto:Mamm-accred@acr.org)

5. ACR staff will acknowledge the receipt of the complaint by the letter to the patient (or facility), obtain a signed Serious Consumer Complaint Inquiry Release Authorization from the patient, request a response from the facility in writing and provide a summary of its resolution to the patient.
6. Unresolved complaints will be forward to the senior director of the Breast Imaging Accreditation Programs for further investigation, FDA notification or other action as appropriate.
7. Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received.

#### **CORRESPONDING POLICIES:**

Source:

Date Approved: 12/07

Date Effective: 12/07

Date Revised: 2/10, 6/12, 3/14

Date Reviewed: 9/16