

## **Veterans Health Administration Mammography Facilities**

• Please read •

The Veterans Health Administration comprises a very small core of mammography sites when compared with the 10,000+ mammography facilities which are accredited nationally to perform mammography services. As a result, it is neither reasonable nor feasible to expect the American College of Radiology (ACR) to specifically modify all their forms to reflect the special circumstances of the VHA as they relate to mammography quality standards.

As you may be aware, Public Law 102-539, the Mammography Quality Standards Act (MQSA), and the Food and Drug Administration (FDA) Final Rule include all private sector and other governmental mammography facilities but specifically exclude the Veterans Health Administration from coverage under the MQSA. However, the Under Secretary for Health voluntarily adopted many of the FDA mammography standards and Congress passed Public Law 104-262, which requires the VHA to implement equivalent quality standards. VHA is consistent with and no less stringent than the MQSA standards. The terminology "consistent with" does not mean "exactly the same as", therefore some of the items contained in the FDA Final Rule, and referenced in ACR documents do not apply to VHA mammography facilities. For example;

- 1. Your packet may contain an "MQSA Information Release Authorization" under which the ACR is authorized to release MQSA related information to the FDA.
  - VHA mammography facilities are <u>not</u> required to complete or sign this form, as the FDA does not have any regulatory jurisdiction over VHA facilities. Remember VHA facilities are specifically excluded from coverage under the MQSA. Data similar to that, which ACR now releases to FDA about private sector facilities, is provided without the need to sign a release to the VHA Mammography Office. There is no reason to release the information to FDA since the VHA is excluded from coverage. The VHA Mammography Office currently receives information about the ACR accreditation of VHA facilities and issues the VHA facility's certification. VHA facilities may wish to mark this form as 'N/A' or 'Not Applicable' and return it to ACR.
- 2. Reference may be made in a number of places to the "FDA certificate" or "certified by FDA" or the "FDA will be notified".
  - Neither the FDA nor any certification body other than the VHA can certify a VHA facility. FDA is
    precluded by the MQSA from providing certification to VHA facilities. The VHA Mammography
    Office is FDA's mirror counterpart in VHA and that office provisionally and fully certifies VHA
    facilities.
- 3. References may be made in ACR documents to State inspectors and MQSA makes reference to States in other roles.
  - Congress mandated through Public Law 104-262 that State agencies will not inspect VHA facilities or be involved in their oversight.

ACR has been very supportive in their accreditation process by the inclusion of the reference to VHA in the ACR MAP Entry Application, which indicates a clear distinction between the two programs.

If you have any questions or comments please feel free to contact Lisa Wall, Assistant Director, National Radiology Program Office, through the VHA Mammography Office (10P4D), 3022 Croasdaile Drive, Suite 101, Durham, NC 27705, by telephone (919) 384-8593 or email Lisa.Wall@va.gov