**Mammography Equipment Evaluations under MQSA's Final Regulations**

There appears to be confusion in the mammography community about the regulatory requirements for equipment evaluations and the scope of such evaluations. The purpose of this note is to clarify these requirements. For additional clarifications and guidance regarding this issue, please refer to FDA's Policy Guidance Help System and other documents at this website.

According to Section 900.12(e)(10) of the regulations, mammography equipment evaluations must be conducted by a medical physicist for **x-ray units and processors that are newly installed, have been disassembled and reassembled, or have undergone major repairs (see Quality Assurance/Equipment/Equipment Evaluations in the Policy Guidance Help System)** Furthermore, such evaluations "shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section." For a new x-ray unit, the word "applicable" refers to the following:

1. Performing all the annual tests listed in section (e)(5) [except (e)(5)(viii), which need not be included if the new unit is not the first one to be accredited in the facility], the "other modality" tests listed in (e)(6) (if applicable), and the phantom image test listed in (e)(2); and

2. Verifying that the new x-ray unit meets the equipment standards listed in Sections (b)(1-10). These standards relate to the design aspects of the unit as provided by the manufacturer. Furthermore, if the new unit is the first and/or the only one at the facility, then (b)(11), (b)(12), (b)(14), and (b)(15), which relate to the screen-film combination and the lighting and viewing conditions used at the facility, must also be verified.

The above items are also listed in the 1999 edition of the ACR manual under "MQSA Requirements for Mammography Equipment" as well as on their website.

Note that an evaluation of the facility's QA program, including the QC tests and corrective actions taken by the facility, is not included in equipment evaluations (as described in paragraphs 1 and 2 above). However, such an evaluation is always included in the annual survey.

For a new processor, the "applicable" equipment evaluation tests include the following:

1. Sensitometric testing as described in 900.12(e)(1)
2. Phantom testing as described in 900.12(e)(2)
3. System artifact evaluation as described in 900.12(e)(5)(ix)
4. Dose determination as described in 900.12(e)(5)(vi) – if clinical techniques increase significantly
5. Verification of the appropriate processing solutions as described in (900.12(b)(13)

Note also that these processor evaluations must include all processors used clinically by the facility, even those at remote sites (if any).