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The printing issue relates to MQSA Quality Mammography Standards 21 CFR 900.4(c)(2)(viii)(C) and 900.12(c)(5)(iii), which specify that, on mammography images, the view name and laterality shall be displayed near the axilla. As part of the software upgrade, a new label is being provided to clarify the labeling of images viewed on the AWS.

Policy Guidance Help System - MQSA Alternative Standard #6 ...

Mammography Quality Standards Act (MQSA) regulations have been in effect for more than 10 years, so a review at this time is appropriate to identify areas in need of enhancement. In addition to making suggestions for changes and possible additions to enhance the quality of mammography, the Committee examined the current regulations and Food and Drug Administration (FDA) data from inspection ...

3 MQSA Regulations, Inspections, and Enforcement ...

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