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number of
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needed to treat
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[3, 5-7].

Therefore,
minimally
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is preferable to
open surgical
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associated with
low complication
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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

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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.

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Standard #6 . . .

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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

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enhancement. In addition to making suggestions for changes and possible additions to enhance the quality of mammography, the Committee examined the current regulations and

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