**Section 370.APPENDIX B Mammography Phantom Image Evaluation**

Mammography phantom image evaluation shall be performed using the procedure below. The evaluation shall be performed weekly as a part of the quality assurance program. The evaluation shall be performed with the mammography phantom specified in Section 370.20 of this Part.

a) Equipment necessary for mammography phantom image evaluation includes a densitometer, the mammography phantom and mammographic cassette and film.

b) Load film in the mammographic cassette according to the manufacturer's instructions.

c) Place the properly loaded cassette in the cassette holder.

d) Place the mammography phantom on the breast support assembly (BSA) so that the edge of the phantom is aligned with the chest wall side of the BSA. Align the phantom so that the masses in the phantom are nearest the chest wall edge of the BSA and the fibers in the phantom are away from the chest wall edge of the BSA. If the mammography machine has the capability of automatic exposure control, place the phantom so that the phantom covers the phototimer sensor.

e) Position the compression device so that it is in contact with the phantom.

f) Select the technique factors used most frequently in the clinical setting for a 4.2 centimeter compressed breast and make an exposure of the phantom.

g) Process the film in the processor used for clinical mammography films.

h) Examine the processed image for areas of non-uniformity of optical density and for the presence of artifacts due to dirt, dust, grid lines or processing.

 AGENCY NOTE: If any of the problems noted above are evident on the processed image, the mammography machine film processor and film cassette(s) should be evaluated and the problem corrected. The phantom image evaluation should be repeated after the problem is corrected.

i) Measure and record the optical density of the film near the center of the phantom image. The optical density of the film at the center of the image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

j) Examine the phantom image and count and record the number of masses visualized. Repeat this procedure for the speck groups and the fibrils and record the number of objects visualized. There are a total of 16 imaging objects (5 masses, 5 speck groups and 6 fibrils) in the phantom. Evaluation criteria for objects visualized in the phantom image are in Section 370.110(b)(3) of this Part. As a minimum, the objects that must be visualized in the phantom image are:

1) The masses that are 0.75 millimeter or larger (a total of 3 masses);

2) The speck groups that are 0.32 millimeter or larger (a total of 3 speck groups);

3) The fibrils that are 0.75 millimeter or larger (a total of 4 fibrils).

AGENCY NOTE: The phantom image should be compared with previous films, including the original phantom image, to determine if subtle changes are occurring from week to week.