Sample Lay Letter for Abnormal Finding (to be used with BI-RADS® 4-5)

Name of Facility, Address and Phone Number Name of Patient/ID Date of Breast Imaging

Dear Patient:

As we discussed at your recent visit, your [mammogram or breast ultrasound or breast MRI] showed an *abnormality* that requires a biopsy. The only way that you can be sure that the abnormality is benign (not cancer) is to sample or surgically remove the area of concern and send these samples for pathological analysis. When these results are available, your health care provider or our facility will contact you concerning the results and any follow up tests or appointments that may be required.

Even though mammograms are the best method we have for early detection, not all cancers are found with mammograms. If you feel a lump or have any other reasons for concern, you should tell your health care provider.

<Select one: Required for Mammography lay letters per FDA >

[For mammography patients with non-dense breasts:]

Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation. (see § 900.12(c)(2)(iii) in the final rule)

- OR -

[For mammography patients with dense breasts:]

Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation. (see § 900.12(c)(2)(iv) in FDA final rule)

-

Your images will become part of your medical record at [facility name]. They will be on file for your ongoing care. If, in the future, you change health care providers or go to a different location for a mammogram, you should tell them where and when this [mammogram or breast ultrasound or breast MRI] was done.

Thank you for allowing us to help meet your health care needs.

Sincerely,

Jane Smith, M.D. Interpreting Radiologist