INFORMATION NOTICE 2017-M1

January 2017

Enhancing Quality Using the Inspection Program (EQUIP)

All mammography facilities are required to initiate the EQUIP program within their mammography program.

IDPH is issuing this notice to inform mammography facilities of FDA's initiative regarding EQUIP. Inspections containing EQUIP questions began on January 1, 2017 and 2017 will be an educational year. Enforcement starts in 2018.

When your 2017 annual inspection is scheduled, documents specific to EQUIP will be sent along with your inspection confirmation notice. The same documents are attached with this information notice. The EQUIP process will be discussed at close out of your annual inspection and you are encouraged to invite all affected staff members to attend.

Following are the questions and sub questions introduced by EQUIP:

Quality Assurance — Clinical Image Corrective Action

1. Does the facility have procedures for corrective action (CA) when clinical images are of poor quality?

(a) Do the procedures include a mechanism for providing ongoing IP feedback on image quality to RT's or other designated facility personnel?

(b) Do the procedures require documenting any corrective actions taken and documenting the effectiveness of any corrective actions taken?

Clinical Image Quality

2. Does the facility have procedures to ensure that clinical images continue to comply with the clinical image quality standards established by the facility's accreditation body?

(a) Do the procedures include a mechanism for regular reviews of image quality attributes of a sample of mammograms performed by each active RT and a sample of mammograms accepted for interpretation by each active IP?

(b) Is there documentation of such review since the last inspection?

Quality Control

3. Does the facility have a procedure for LIP oversight of QA/QC records and corrective actions?

(a) Does the procedure include requirements for LIP oversight of QA/QC records, including review of the frequency of performance of all required tests?

(b) Does the procedure include requirements for LIP review to determine whether appropriate corrective actions were performed when needed?