



DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JOHN W. POLANOWICZ
SECRETARY

CHERYL BARTLETT
ACTING COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Environmental Health
Radiation Control Program
Schrafft Center, Suite 1M2A
529 Main Street, Charlestown, MA 02129
(617) 242-3035 (617) 242-3457 - Fax

Dear Mammography Facility:

A representative from the Radiation Control Program will be conducting the annual mammography facility inspection. Please refer to the guidelines below to help you prepare for the upcoming inspection.

The inspection is designed to meet the requirements of both the Massachusetts Mammography Facility Licensing Act and the Federal Mammography Quality Assurance Act (MQSA). The inspection will be as non-disruptive to your facility's normal activities as possible.

The inspection begins with a brief meeting with the licensee (MQSA certificate holder) and concludes with an exit interview at which time preliminary findings are discussed with the licensee. The radiation control officer conducting the inspection will point out the differences between the Massachusetts mammography regulations and MQSA regulations.

Your facility will be sent two written reports, under separate cover, of the inspection results. One report will be sent relative to the Massachusetts Mammography Facility License regulation. The second report will include a summary listing of findings relative to the Federal MQSA regulations.

The inspection will cover the following areas: equipment performance; review of quality assurance records and test results, personnel qualifications, medical records, and medical audit and outcome analysis records (required under MQSA). During the inspection, five cases will be reviewed to determine if your medical record policies and technologist positioning techniques have been followed.

In order to facilitate the inspection process, I ask that the following items be available for review on the day of the inspection:

1. The two most recent medical physicist reports on each mammography x-ray machine;
2. Processor PM reports for previous 24 months;
3. X-ray service reports of calibrations for previous 36 months;

4. List of names and qualifications of individuals responsible for:
 - a. QA supervision,
 - b. performance of QA tests,
 - c. QA technologists,
 - d. equipment repair and service firms.
5. List of all elements that have an impact on image quality;
6. Limits of parameters of acceptability for each element;
7. Brief description of QA tests performed,
8. Frequency of each QA test;
9. Blank forms used for each QA test;
10. Protocol for correcting each QA finding that does not fall within acceptable limits;
11. List of equipment used to perform QA tests;
12. Personnel credentials (certifications and training documents) for:
 - a. Responsible Physician;
 - b. Interpreting Physician(s);
 - c. Medical Physicist;
 - d. Mammography Radiologic Technologist(s)
13. Medical audit and outcome analysis policies, procedures, and records (MQSA requirement).
14. Documentation showing continued experience for the Mammographers (200 exams during the previous 24 months).

Generally, the inspection process requires approximately 25-30 minutes with each x-ray unit. During this time the x-ray unit is checked for alignment (MQSA requirement), output at the most commonly used technique and half-value-layer, and an image is made of a mammography phantom for image quality evaluation. The facility's darkroom and film processor are also evaluated.

The review of the procedures, QA manual, QA records, and alike typically takes 4-5 hours.

The facility is expected to have available for review records showing that the 15 hours of C.M.E.'s for the physicians and physicist have been fulfilled in the last 36 months from the date of inspection.

Should you have any questions about the required annual inspection process please contact me at 617-242-3035 x 2011.

Karen Farris

Sincerely,

Karen Farris RT(R)(M), Supervisor
Mammography/Healing Arts
Radiation Control Program