



JENNIFER M. GRANHOLM
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

JANET OLSZEWSKI
DIRECTOR

February 28, 2008

Joanne Laskowski, R.T.(R.)(M.)
St. John Macomb Breast Center
28363 Hoover Road
Warren, Michigan 48093

Mammography Facility Registration Number: 20289

Dear Ms. Laskowski:

The Radiation Safety Section examined the mammography facility at the above address on February 7, 2008, to determine compliance with the *Ionizing Radiation Rules* of the State of Michigan, applicable radiation statutes, and the federal Mammography Quality Standards Act (MQSA). Results of the state inspection are presented below. Results of the MQSA inspection were left with the facility at the time of the inspection.

The results of the examination are presented below. Items of noncompliance with the rules are numerically designated.

Radiation Machine Registration Number X060987, Room 3

1. **Rule 649.** The collimator light field was not aligned with the x-ray field within 2% of the source-image distance.

Radiation Machine Registration Number X060987, Room 3

2. **Rule 652(2).** Reproducibility for the automatic exposure control system was not within required limits.

Radiation Machine Registration Number X053451, Room 1

3. **Rule 652(3).** The automatic exposure control system did not maintain image optical density to within ± 0.2 of the average as the kVp was varied within the clinically employed range and as attenuator thickness was varied from 2 to 6 centimeters for each clinically employed kVp.

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BY: *Sub.*

Patient Radiation

Our survey of the mammography equipment included determination of patient radiation dose using technique settings used for average-size, average-density breasts. The half-value layers in millimeters of aluminum, patient skin entrance exposures in milliroentgens (mR), and estimated mean glandular doses in millirads are reported below:

<i>Machine</i>		<i>Density</i>	<i>Resultant</i>	<i>Half-value</i>	<i>Entrance</i>	<i>Mean</i>
<u>Reg. No.</u>	<u>KVp</u>	<u>Setting</u>	<u>mAs</u>	<u>Layer</u>	<u>Exposure</u>	<u>Glandular</u>
						<u>Dose</u>
X050888	26	0	95	0.33	945	159
X053451	26	0	95	0.34	934	161
X060987	28	0	67	0.37	810	151
X061732	28		70	0.31	671	108

The phantom images appeared to meet the required minimum imaging standards.

Please refer to the *Mammography Inspection Data Sheets* for a detailed analysis of the mammography machine checks and information concerning quality assurance.

Response

Written notice of corrective action for the indicated items of noncompliance is requested by April 1, 2008.

For your convenience, a notification form is enclosed which can be filled in, signed, and returned to indicate completion of corrective action.

Please be sure to **indicate the facility registration number** in correspondence. If there is more than one machine registered on the certificate, please **indicate the machine registration number**.

We remind you that if the *MQSA Inspection Report* contained level 2 or repeat level 3 violations, a response pertaining to those violations must be sent to the Indianapolis office of the FDA within 30 days of receiving the *MQSA report*. The *MQSA Inspection Report* was issued at the time of the inspection.

For your information, items of noncompliance are subject to reinspection with possible assessment of a reinspection fee. In addition, items of noncompliance can result in withdrawal of mammography authorization. A timely notice of corrective action, however, may be accepted by the Department in lieu of a reinspection and fee, and such notice may also prevent the initiation of actions to withdraw the mammography authorization.

An invoice for the mammography machine inspection fee is enclosed. Payment of the fee is now due. Failure to pay this fee may result in the initiation of actions to withdraw your mammography authorization.

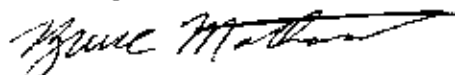
Mammography machine inspection certificates will be issued following receipt of notice of corrective action for all items of noncompliance.

Please share this report with the Radiation Protection Supervisor, Richard G. Hayes, M.D.

Contact Information

Should there be any questions regarding this report or if we can be of further assistance in radiation protection matters, please contact us (586) 446-0200

Sincerely,



for: Dennis J. Aurand, M.S., Health Physicist
Radiation Safety Section
Division of Health Facilities & Services
E-mail: djauran@michigan.gov
Web site: www.michigan.gov/rss

Enclosures: *Mammography Inspection Data Sheets*
Notification Form
Mammography Inspection Invoice