Inspections, Compliance, Enforcement, and Criminal Investigations

Hudson Radiology Center 1/28/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Jersey District Office
Central Region
Waterview Corporate Center
10 Waterview Blvd. 3'd Floor
Parsippany, New Jersey 07054
Telephone: (973) 331-4900
FAX: (973) 331-4969

WARNING LETTER

January 28, 2014

Certified Mail
Return Receipt Requested

Re: MQSA Inspection ID 1171840018
FEI 1000526934

Ata Chandhry, Owner
Hudson Radiology Center of NJ
410 Centre St.
Nutley, NJ 07110

14-NWJ-04

Dear Mr. Chandhry:

On 04/29/2013, a representative of State of New Jersey, acting on behalf of the Food and Drug Administration (FDA) inspected your facility located at 657-659 Broadway, Bayonne, NJ 07002. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document "*Important Information about Your MQSA Inspection*" that the inspector mailed to Louise Syperski, Facility Supervisor, on 05/02/2013. The violations are again identified below:

Level 2: The FFDM manufacturer QC (excluding monitor and printer QC) procedures for digital unit

3, Lorad (Hologic), SEL, room Mammography were not followed. [See 21 CFR 900.12(e)(6)]

Level 2: The manufacturer recommended Printer QC procedures for digital unit 3, Lorad (Hologic), SEL, room Mammography were not followed. [See 21 CFR 900.12(e)(6)]

Level 2: The manufacturer recommended QC procedures for the monitor for digital unit 3, Lorad (Hologic), SEL, room Mammography were not followed. [See 21 CFR 900.12(e)(6)]

Level 2: Failed to produce documents verifying that the interpreting physician JOHN LYONS met the requirement of having 8 hours of training in the new mammographic modality. [See 21 CFR 900.12(a)(1)(ii)(C)]

Level 2: Medical audit and outcome analysis was not done separately for each individual at site Hudson Radiology Center of NJ. [See 21 CFR 900.12(f)(1)]

Level 2: Medical audit and outcome analysis was not performed annually at site Hudson Radiology Center of NJ. [See 21 CFR 900.12(f)(2)]

Level 2: There is no designated audit (reviewing) interpreting physician for site Hudson Radiology Center of NJ. [See 21 CFR 900.12(f)(3)]

You have failed to respond to the MQSA Facility Inspection Report as requested in the document "Important Information about your MQSA Inspection" and failed to respond to additional communication attempts by our office on 07/11/13, 08/08/13, 08/12/13, and 08/29/13.

On 01/06/2014, a representative of the FDA performed an MQSA follow-up inspection of your facility. This MQSA follow-up inspection revealed that your facility failed to correct the violations identified below.

Level 2: The FFDM manufacturer QC (excluding monitor and printer QC) procedures for digital unit 3, Lorad (Hologic), SEL, room Mammography were not followed (REPEAT). [See 21 CFR 900.12(e)(6)]

Level 2: The manufacturer recommended Printer QC procedures for digital unit 3, Lorad (Hologic), SEL, room Mammography were not followed (REPEAT). [See 21 CFR 900.12(e)(6)]

Level 2: The manufacturer recommended QC procedures for the monitor for digital unit 3, Lorad (Hologic), SEL, room Mammography were not followed (REPEAT). [See 21 CFR 900.12(e)(6)]

Level 2: Failed to produce documents verifying that the interpreting physician JOHN LYONS met the requirement of having 8 hours of training in the new mammographic modality (REPEAT). [See 21 CFR 900.12(a)(l)(ii)(C)]

Level 2: Medical audit and outcome analysis was not done separately for each individual at site Hudson Radiology Center of NJ (REPEAT). [See 21 CFR 900.12(f)(l)]

Level 2: Medical audit and outcome analysis was not performed annually at site Hudson Radiology Center of NJ (REPEAT). [See 21 CFR 900.12(f)(2)]

Level 2: There is no designated audit (reviewing) interpreting physician for site Hudson Radiology Center of NJ (REPEAT). [See 21 CFR 900.12(f)(3)]

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, the FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review (AMR)
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring
- requiring your facility to notify patients who received mammograms at your facility, and their referring healthcare providers, of the deficiencies, the potential harm resulting from such deficiencies, appropriate remedial measures, and other relevant information
- seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate
- seeking a court injunction against your facility

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to the FDA within fifteen (15) working days from the date you receive this letter. Your response should address the findings listed above and include:

1. the specific steps you have taken, or will take, to correct the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

3. sample records that demonstrate proper record keeping procedures.

Please submit your response to this letter to:

Jeffrey Sincek
Regional Radiological Health Representative
U.S. Food and Drug Administration
580 South High Street, Suite 140
Columbus, OH 43215
Phone: (614) 227-5780 x 111
Fax: (614) 227-5795

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection(s) of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of the FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057, by phone at 1 (800) 838-7715 or the Internet at http://www.fda.gov/cdrh/mammography/index.html[1].

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Jeffrey Sincek, Regional Radiological

Health Representative at (614) 227-5780 ext. 111.

Sincerely yours,
/S/

Diana Amador Toro
District Director
New Jersey District

cc:

Louise Syperski, Facility Manager
Hudson Radiology Center of NJ
657-659 Broadway
Bayonne, NJ 07002

Ramona Chambus, Supervisor
Bureau of X-Ray Compliance
NJDEP
P. 0. Box 420, Mail Code 25-01
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Priscilla F. Butler, M.S., FAAPM
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Page Last Updated: 06/18/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

1. http://www.fda.gov/cdrh/mammography/index.html