Accepted 12/29/08

PRINTED: 12/16/2008
FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050496	(X2) MULTIPLE CONSTRUCTION A. BUILDING ______ B. WING ______	(X3) DATE SURVEY COMPLETED C 11/20/2008

RECEIVED DEC 26 2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
JOHN MUIR MEDICAL CENTER - CONCORD C.	2540 EAST ST CONCORD, CA 94520

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E 000	Initial Comments THIS STATE-2567 HAS BEEN AMENDED TO ADD T22 DIV5 CH1 ART7 - 70707(b)(2) AND 70707(d) AND TO REMOVE "ADVERSE PENALTY NUMBER: 020005673". The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident. Entity reported incident number. CA00167372 Representing the Department: [redacted] HFEN The inspection was limited to the specific entity reported incident investigated and does not represent a full inspection of the facility.	E 000	**(A-D) Corrective Actions**: To ensure that written policies and procedures are developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration, the hospital will provide procedures approved by the medical staff and administration in accordance with Statue T22 DIV5 CH1:ART3-70253(b) Radiological Service General Requirements and ART7-70707 Patients' Rights (b) and (d) – The following actions were initiated: 1. <u>Staff Educated Regarding Hand-Off Communication</u> Educational materials were quickly and widely disseminated to all Medical Imaging (MI) and nursing staff to emphasize the importance and need for hand-off communication, including special needs such as fall risk. Message was communicated via e-mail and in person by managers and supervisors. **Responsible Person**: [redacted] Director, Acute Care Services.	Oct 28 2008
E 448	T22 DIV5 CH1 ART3-70253(b) Radiological Service General Requirements (b) Written policies and procedures shall be developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. This Statute is not met as evidenced by: See below.	E 448		
E1945	T22 DIV5 CH1 ART7-70707(b) Patients' Rights (b) A list of these patients' rights shall be posted	E1945		

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] TITLE: Director of Operating PCS (X6) DATE: 12/23/08

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E1945	Continued From page 1 in both Spanish and English in appropriate places within the hospital so that such rights may be read by patients. This list shall include but not be limited to the patients' rights to. This Statute is not met as evidenced by: See below	E1945	1.1 Staff Received Formal On-Line Education Regarding Hand-Off Communication An on-line self study module was developed for mandatory completion by all MI, Radiation Oneology, Non-Invasive Cardiology and nursing staff. Self-study module was available on 10/30/08 and was completed by 747 total employees as of 12/22/08. In Medieal Imaging, including CT, Nuelear Medicine and Ultrasound, 47 of 49 employees have completed the training. The two MI employees who have not yet completed are on leave of absence and will complete prior to returning to work. **Responsible Person:** [redacted] Coordinator, Staff Education 2. New Fall Risk Policy Developed A new Medical Imaging policy outlining special precautions and processes for managing inpatients & ED patients with fall risk within the MI Department was developed. New policy was applied to all Medical Imaging areas at all John Muir Health Campuses. **Responsible Person:** [redacted] Medical Imaging Director	**Dec 20 2008** **Nov 3 2008**
E1947	T22 DIV5 CH1 ART7-70707(b)(2) Patients' Rights (b) A list of these patients' rights shall be posted in both Spanish and English in appropriate places within the hospital so that such rights may be read by patients. This list shall include but not be limited to the patients' rights to: (2) Considerate and respectful care. This Statute is not met as evidenced by: See below	E1947		
E1969	T22 DIV5 CH1 ART7-70707(d) Patients' Rights (d) All hospital personnel shall observe these patients' rights. This Statute is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to follow its own policy and procedure for "Restraining Patient for Radiological Exams" and observe a patient's right for considerate and respectful care while a patient was in the radiology department. As a result, Patient 7 fell off the procedure table, hit and ruptured her right eye globe, resulting in right	E1969		

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E1969	Continued From page 2 eye blindness. THIS EVENT CONSTITUTED AN IMMEDIATE JEOPARDY (IJ), WHICH PUT THE HEALTH AND SAFETY OF PATIENT 7 AT RISK WHEN THE RADIOLOGY DEPARTMENT STAFF FAILED TO IMPLEMENT THE HOSPITAL WRITTEN POLICY AND PROCEDURE FOR "RESTRAINING PATIENT FOR RADIOLOGIC EXAMS." THIS FAILURE RESULTED IN BLINDNESS OF PATIENT 7'S RIGHT EYE. THUS, THESE VIOLATIONS CAUSED, OR WERE LIKELY TO CAUSE, SERIOUS INJURY OR DEATH TO THE PATIENT Findings: On 11/6/08, review of the hospital Policy and Procedure for "Restraining Patient for Radiologic Exams" showed that "If a patient must be left alone in a procedure room, every caution will be taken to secure the patient (Velcro, table band, side rails if available). Assessment of patient status is the technologist ' s responsibility along with any security of a patient's well being during the procedure." Review of the medical record on 11/6/08 at 2.45 p.m. showed that the hospital admitted Patient 7 on 9/17/08 from the emergency room with the complaint of right sided pain, possible small bowel obstruction. Patient 7 had a history of metastatic ovarian cancer and chronic pain. On 10/18/08 at 8:00 a.m., the nurse documented in a "Shift Assessment" that Patient 7 was withdrawn and had visual hallucinations. At 3:15 p.m., Patient 7 was "Sleepy/arousable, with periods of confusion, disoriented at times" and had a Fall Risk Assessment Score of 8 (meaning	E1969	2.1 Staff Educated Regarding New Fall Risk Policy All Medical Imaging staff received individual or group training regarding the new policy for managing fall risk patients. Education also included the use of SBAR [hand-off communication form], shift-to-shift communication and communication with nursing staff anytime the patient has a significant wait between procedures. The two MI employees who have not yet completed are on leave of absence and will complete prior to returning to work. **Responsible Person:** [redacted] Clinical Manager, Medieal Imaging. 2.2 RNs Assigned to MI Educated Regarding New Fall Risk Policy All float pool RNs assigned to work in MI received training. **Responsible Person:** [redacted] Director, Acute Care Services 2.3 All Radiologists Educated Regarding New Fall Risk Policy All Radiologists received e-mail communication regarding the event and the changes put in place in response to the event. Communication included details of new fall risk policy. **Responsible Person:** [redacted] Chairman, Department of Medical Imaging, Concord Campus	Nov 7 2008 Nov 29 2008 Nov 3 2008

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E1969	Continued From page 3	E1969		

the patient had a high risk of falling).

Review of "Physician's Orders" showed that on 10/18/08 at 1:00 p m. the physician ordered a series of x-rays of Patient 7's small bowel.

On 10/19/08 at 8 a.m. and then at 3.15 p.m., the nurses documented that Patient 7 was "Sleepy/arousable, with periods of confusion, disoriented at times, speech/cognition: appropriate, answers questions, and had a Fall Risk Assessment Score of 8."

The radiologist wrote on 10/19/08 at 4:50 p.m., that Patient 7 "was found down on the floor, calling for help in x-ray exam room. In distress about being on floor. Disoriented to place and time" and that there was blood coming from the patient's right eye. Head and orbital CT's (computed tomographies) were ordered At 6:15 p.m., the radiologist documented that Patient 7 had a ruptured right globe (eyeball). At 9:05 p.m., the ophthalmologist (eye doctor) saw Patient 7 and documented "ruptured globe and depression of the medial wall, absent right lens," with treatment options of surgery for "attempt repair or enucleation (removal of the eyeball)" or monitoring and antibiotic ointment. Patient 7 had no light perception in the right eye.

Review of the "Operative Report", dated 10/21/08, showed that the ophthalmologist discussed his/her findings "at length with the family. Given that she (Patient 7) was a terminal metastatic ovarian cancer patient. the family opted to not do surgery at that time. However, I had told them that, if she was to undergo anything else requiring general anesthesia, then I may as well explore and repair her eye at that time " Patient 7 underwent eye surgery on

2.4 New Fall Risk Policy Included in New Employee Orientation — Nov 3 2008

The new employee orientation program for Medical Imaging was modified to include educating all new employees about management of fall risk patients. This was applied to all Medical Imaging areas at all John Muir Health Campuses.

Responsible Person: [redacted] Medical Imaging Director

2.5 Staff Understanding of New Fall Risk Policy Assessed — Dec 19 2008

An audit tool was developed 11/7/08 for the purpose of assessing staff competency and understanding of the new fall risk policy and hand-off communication expectations. Auditing of all Medical Imaging staff commeneed on 11/10/08. First ronnd assessment of MI technologist staff, completed 12/3/08, resulted in 92% overall compliance. Staff who fell below 100% were re-educated and re-assessed. Final assessment showed staff compliance at 100%. Assessment will be conducted quarterly in 2009 and results reported to Patient Safety Committee.

Responsible Person: [redacted] Medical Imaging Direetor

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E1969	Continued From page 4 10/21/08. Patient 7's right eye remained blind. During the facility's investigation of the incident, X-ray Tech A documented in a written statement (not dated) that she received Patient 7 at 3:30 p.m., that she took Patient 7 into room 8, moved Patient 7 from the gurney to the exam table with the help of two other technicians, and took two films. X-ray Tech A further documented that at about 4 p.m., the radiologist told her that another film was needed at 4:45 p.m. Patient 7 chose to "stay where she was for a little while, until it was time for the final film" rather than to move back to the gurney. According to the written statement, X-ray Tech A left the department at 4:40 p.m. to do a stat (urgent) portable film. X-ray Tech B stayed in the department. During a telephone interview on 11/6/08 at 10:20 a.m., X-ray Tech B stated that he had stopped into room 8 because Patient 7's IV (intravenous) pump was alarming and that at the time, Patient 7 was on her back on the exam table covered with several blankets up to her chin. X-ray Tech B further stated that he was in the office when he heard a scream, ran into room 8, and found Patient 7 about two to three feet from the exam table, face down on the floor, and bleeding from her right eye. When asked if Patient 7 was secured to the exam table by a safety strap, X-Ray Tech B stated, "No, I didn't see a safety strap on her." During an interview on 11/6/08 at 9:55 a.m., the Diagnostic Imaging (DI) Manager stated that the expectation for patient monitoring "is that the tech will be aware of the patient condition at all times." When asked if a safety strap was used to secure Patient 7 on the exam table, the DI Manager stated, "No, she didn't have it on."	E1969	3. Implemented New "Patient Monitoring During Intrahospital Transport" Policy Implemented a policy whereby all inpatients and ED patients being transported off unit for treatment, care or testing are assessed for their level of risk based on a 4-level scale. Patients identified as level 3 & 4 are accompanied by an RN whenever they are transported off unit and an RN remains in attendance with the patient while off unit. **Responsible Person:** [redacted] Director, Acute Care Services 4. Added RN staffing to Medical Imaging Staffing A core group of float pool RNs have been trained are now assigned to be stationary in the Medical Imaging Department. One RN is present in the MI Department during day shift, 7 days a week. The role of the Medical Imaging RN is to directly monitor, provide patient care and attend to the physical and psychosocial needs of patients being seen in the MI Department. **Responsible Person:** [redacted] Director, Acute Care Services	**Nov 3 2008** **Nov 3 2008**

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E1969	Continued From page 5 By observation during a tour of the DI Department on 11/6/08 at 10:49 a.m , in the presence of the DI Manager and the Quality Manager, there was an intercom microphone and a video camera aimed at the holding (waiting) area. The camera and the intercom monitors were located in the office, behind a door. The door to room 8 was to the left of the holding area, while the office was located to the right. Room 8 was not visible on the video monitor. To be heard in the office, an x-ray tech had to speak loudly from near the opened door of room 8. Due to the location and setting of both the video and the intercom systems, the radiology staff was unable to monitor/assess the safety of Patient 7 in room 8 from the office.	E1969		