CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050327	A. BUILDING _____ B. WING _____	01/26/2010

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LOMA LINDA UNIVERSITY MEDICAL CENTER	11234 Anderson St, Loma Linda, CA 92354-2804 SAN BERNARDINO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00214803 - Substantiated Representing the Department of Public Health: Surveyor ID # 25179, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(c): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Health and Safety Code Section 1279.1 (c): (c) "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made." The California Department of Public Health verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made. AMENDED REGULATION VIOLATION: Health & Safety Code Section 1280.1 and California	POC Accept NJ 7/7/14	A statement of deficiencies was received by LLUMC for this case on 5/25/2010, and the POC was submitted on 6/3/2010. a) How the correction was accomplished, and dates • Historically, the ability to preliminarily review basic diagnostic studies, such as a film to check placement of a feeding tube, has been understood to be a skill that medical school graduates possess as part of the general practice of clinical medicine; and there has not been a specific enumerated "privilege" nor "capability" to perform such review. Resident supervision for such activities has been general, rather than direct, often taking place during rounds and other patient care discussions rather than observation at the time. Learning opportunities are addressed by a senior resident or attending physician when identified. Each residency program has a Residency Program Director who is responsible to monitor and assure quality of care provided by resident physicians in that program. Issues with the quality of care by a resident within the facilities where the resident works are reported to the program director for review and tracking. Reporting may be by an Attending physician, other residents, unit staff, or anyone else with knowledge of a situation. If a problematic trend/event is identified, it is brought to the attention of the Director of Graduate	

Event ID:7KW911 7/3/2014 5:15:09PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Brenda Bureau TITLE: Chief Quality & Patient Safety Director (X6) DATE: 7/3/14

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s): 1 thru 10

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 60 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	Code of Regulations, Title 22, section 70203 Medical Service General Requirements 1280.1(c) For purposes of this section "immediate jeopardy" means a situation in which the licensee?s noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. AND 70203(a)(2) (a) A committee of the medical staff shall be assigned responsibility for: (2) Developing, maintaining and implementing written policies and procedures 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. Based on interview and document review, the facility failed to ensure medical staff supervised the care provided by residents (physicians still in training and not granted medical staff privileges) in accordance with the facility's policies and procedures. Specifically, the medical staff failed to follow the policy entitled, "Supervision of Residents," with an effective date 3/14/05 (March 14, 2005) resulting in Patient 1 receiving a tube feeding into the lung instead of the stomach on [redacted]10[redacted]4, 2010). Specifically, Resident 1 misread an X-ray of improper tube placement in the		Medical Education (GME) for appropriate action. Additionally, specific situations impacting patient care (such as this case) are also brought to the attention of the Patient Safety and Reliability Department and the VP for Patient Safety and Quality for investigation and the findings are reported to the Medical Staff Executive committee (MSEC), the Quality Committee of the Board (QCB) and the LLUMC Board. • To ascertain the ability of residents entering the established GME program at LLUMC, an assessment of resident ability to preliminarily review basic diagnostic studies was implemented with the incoming residents by July 1, 2010. Education about the importance of requesting assistance to assure patient safety has been stressed to each group of subsequent PGY-1 residents as part of this process. • ACGME introduced new standards for resident supervision in 2011. LLUMC complied with the revised ACGME requirements by July 1, 2011. • All attending physicians were reminded of their accountability for resident supervision according to Medical Staff Rules and Regulations by memo from the Medical Staff President by June 18, 2010. The issue was discussed at the MSEC meeting on June 7, 2010 and at the Medical Staff Annual Meeting on June 8, 2010. • Additional education for attending physicians in how to enhance the effectiveness of resident supervision was	7/1/10 7/1/11 6/18/10

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	right lung instead of the stomach of Patient 1. Resident 1 informed the nursing staff that Patient 1's tube feeding could be started. There was no documented evidence that Resident 1 received approval or supervision from the supervising physician to confirm that the feeding tube was placed correctly in the stomach. These failures resulted in Patient 1 receiving liquid nutrition into the lung. The patient went into respiratory distress, was placed on a ventilator, and died on [redacted]10 [redacted]010). Review of Patient 1's clinical record on 1/26/10 (January 26, 2010), revealed that the patient was admitted to the facility on [redacted]09 ([redacted] 2009) with a diagnosis of pneumonia. The physician History and Physical dated [redacted]/09 ([redacted] 2009) indicated that the patient had a decreased oral intake and weight loss. Review of the emergency department nursing assessment dated [redacted]09 ([redacted] 2009) at 3:47 PM showed that Patient 1 was alert, awake and cooperative with English being a secondary language. Review of the physician orders dated [redacted]09 ([redacted] 2009) showed an order for a nasogastric tube (NGT-a tube inserted through the nose, down the throat and into the stomach). There was also an order for a nutrition consult for a tube feeding recommendation. Review of the physician orders dated [redacted]09 [redacted], 2009) at 3:40 PM showed an order		provided throughout 2010-2011 starting with a faculty development session for program directors and chief residents in September 2010. • Attending physicians and residents are instructed to call the Radiology Attending or resident on-call for assistance with review of any radiologic study about which they have any question. • Education to all incoming residents regarding structure of supervision process and the importance of seeking help when unsure of any aspect of medical care was completed during orientation of new residents, July 1, 2010 and has been provided each year subsequently. • An assessment of the knowledge and safety of incoming residents was implemented July 1, 2011. b) Title or position of person responsible for implementing the corrective action: Director, Graduate Medical Education (GME); President, Medical Staff; and Vice President, Quality and Patient Safety c) Monitoring process established to prevent recurrence of the deficiency: • Ongoing review of resident practice by Residency Program Directors and Director, GME • Ongoing review of quarterly QCB and LLUMC Board agenda and minutes	Sept 2010 to June 2011 7/1/10 and annually thereafter 7/1/11 and annually thereafter

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	for a tube feeding of Nepro (a tube feeding formula) to start at full strength at 25 ccs (cubic centimeters) per hour for 12 hours and to increase the tube feeding by 10 ccs per hour every 12 hours until a goal rate of 45 ccs per hour is reached. Review of the nurse's note dated [redacted] 2009) at 1:10 PM, documented that the NGT was inserted into Patient 1. The nurse's note dated [redacted] 2010) at 11:25 PM showed the following: "@ (at) 2315 (11:15 PM) pt (patient) pulled out his NGT. tried reinsertion pt grabbed my hands and said NO. called dr (doctor)...(doctor's name) made aware pt pulled out NGT and refusing reinsertion." Review of the physician order dated [redacted] 2010) at 11:25 PM showed an order to hold (stop) the tube feeding now as the patient refused NGT reinsertion. Review of a nurse's note dated [redacted] 2010) at 2:09 PM showed the following: "Dr. (name) at bedside to update family. Pt agrees to place NG tube." Review of a nurse's note dated [redacted] 2010) at 3:04 PM showed the following: "...NG tube placed. Flexiflo (a type of nasogastric tube) verified by air bolus and auscultation (verified the proper placement of the NGT by injecting air		• Oversight of program managed by Office of Graduate Medical Education; reports provided on an annual basis to Quality Committee of the Board • Aggregate reports by service are used to evaluate the effectiveness of the program • Ongoing evaluation of residents by attending physicians is conducted on a periodic basis and provided to the GME office. • Individual reports by resident are used to evaluate the skill, knowledge and behavior of each resident. • Results of assessment of knowledge of specific diagnostic tests and knowledge of patient safety of incoming residents was completed by July 2010 and monitored each year subsequently.	

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	Into it and listening with a stethoscope over the stomach to hear the air bubble into the stomach), 2nd RN (Registered Nurse) verification...PO (by mouth) meds (medications) given via NG. Pharmacy called for tube feeding..." On [redacted] 10 ([redacted] 2010) at 7:15 PM the nurse's note showed that the NGT was found on the bed (not in the patient). On [redacted] 10 ([redacted] 2010) at 10:45 PM the nurse documented that they tried to replace the NGT twice but were unable to verify proper placement of the tube. Review of the nurse's note dated [redacted] 10 ([redacted] 2010) at 11:25 PM, documented that the physician (Resident 1) was informed regarding the unverified placement of the NGT and the physician (Resident 1) ordered a KUB X-ray (an X-ray of the chest and abdomen to see whether or not the NGT was in the patient's stomach). The X-ray was completed on [redacted] 10 ([redacted] 2010) at 12:02 AM. Review of the Physician telephone orders dated [redacted] 0 ([redacted] 2010) at 12:25 AM shows the following: "OK to use NGT." In an interview on 2/22/10 (February 22, 2010) at 10:33 AM with RN 1(Patient 1's nurse on [redacted] 10 ([redacted] 2010) during the night shift), RN 1			

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	stated that when the NGT was placed on [redacted]10 [redacted] 2010), she could not hear anything in the stomach so RN 1 got RN 2 to double check her NGT placement. RN 1 stated that RN 2 could not verify that the NGT was in the stomach. An X-ray was ordered by the physician and after the X-ray was done the physician called back and told me it was OK to use the NGT. The feeding was restarted around midnight. RN 1 stated that she did not notice that Patient 1 had any distress during the night. In an interview with RN 3 (the nurse that had Patient 1 on [redacted]10 [redacted] 2010) during the day shift) on [redacted]10 ([redacted] 2010) at 10:20 AM, RN 3 stated that the patient was assessed around 7:00 or 7:30 AM. The patients pulse oximetry (a monitoring device that measures oxygen saturation in the blood) was 97 to 98% (normal 97 to 100%) the morning o[redacted]10 [redacted] 2010). RN 3 stated that fine crackles were heard in Patient 1's lungs, but that the finding was not unusual for the patient as the patient "had been like that." RN 3 stated that around 10:00 AM on [redacted]10 [redacted] 2010) Patient 1's oxygen saturation alarm went off and RN 3 repositioned the pulse oximeter probe from the patient's ear to the patient's finger. RN 3 stated that the reading was 99% initially but then it slowly declined and the patient looked "dusky". RN 3 stated he then called the "Rapid Response Team." RN 3 stated that the patient was on continuous NGT feedings. Review of a progress note titled "Code Blue Team			

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	Note" dated [redacted] 2010) at 10:25 AM showed the following: "Came to bedside for Code Blue (cardiac or respiratory arrest team). Code Blue already being run by Sr. (Senior) Resident..Pt. already intubated (a tube place in the trachea or breathing tube to deliver oxygen to the lungs) and received epi (epinephrine-or adrenalin an emergency drug to start the heart when the heart is not beating) x3 (given 3 doses), 1 of atropine (a medication to stimulate electrical activity in the heart) for PEA (pulseless electrical activity-the heart is generating a wave on the EKG (electrocardiogram) but is not beating)...Pt to be transferred to MICU (medical intensive care unit) for further care/management." Review of the KUB X-ray results from [redacted] 2010) at 12:02 AM showed the following: "A feeding tube is noted, with the tip in the region of the right lung base..." "Findings were recognized by Resident 2 and the radiologist at 10:25 AM [redacted] and were discussed with the patient's attending physician by telephone @ (at) 10:30 AM on [redacted]." Review of a "death note" dated [redacted] 2010)at 4:00 PM showed the following: "Patient was unresponsive to verbal/pain. No pulse, pupils unreactive, no cardiac activity, asystole (no electrical waves noted on a cardiac monitor) on cardiac monitor and vent (ventilator) was stopped.			

14 JUL -7 AM 8:22

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	Patient declared dead o[redacted]0 at 3:35 PM." The Director of Residency Program was interviewed on 2/23/10 (February 23, 2010) at 10:00 AM. He stated (regarding the X-ray taken on [redacted]/10 [redacted]2010) at 12:02 AM) that the (tube placement) was obvious and that (Resident 1) "should have been able to read it." He explained that medical students are trained in medical school to read X-rays and he did not think that a resident's knowledge of reading X-rays needed to be evaluated. The Director of House Staff Training was interviewed 2/23/10 (February 23, 2010) at 1:55 PM. He produced a list of medical procedures that all residents must be evaluated on before residents can perform medical treatment of a patient or issue a treatment order without supervision and approval by a supervising physician. Reading X-rays or determining the position of nasogastric tubes was not on the list of procedures that residents of the facility could perform without supervision or approval of a supervising physician. The Director of House Staff Training advised that the incident with Patient 1 involving the NGT feeding into the lung has facilitated discussions among facility Administrators of the Residency Program regarding evaluation of interns. Review of a facility operating policy entitled, "Supervision of Residents" with an effective date 3/14/05 (March 14, 2005), was reviewed on 2/23/10 (February 23, 2010), and showed the following:			

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	"Residents and fellows who have not been granted Medical Staff privileges shall be consistently subject to supervision by a teaching physician: "Supervision may be direct or general as appropriate. As the resident gains clinical skills, the intensity of supervision will decrease. Supervision may be partially shared by a more senior resident." The policy also states: "In all cases the final responsibility for the supervision of residents and fellows who have not been granted Medical Staff privileges lies with the teaching physician. This responsibility includes ensuring the quality of care provided to patients, patient safety and provision of high quality education." There was no documented evidence that the facility ensured that Resident 1 was competent to read an X-ray to determine correct feeding tube placement and could perform this procedure without the supervision of a teaching physician as per the facility's policy and procedure. The facility was interviewed regarding whether the facility notified the patient's family or responsible parties of the adverse event that occurred on [redacted] 2010. The facility stated, "We have documented evidence that we notified the patient's family members on [redacted] 2010 at 1:45 PM in a half page notation." Failure to develop and implement a facility policy for supervising and evaluating the facility's residents regarding appropriate reading of X-rays to confirm proper placement of an NG tube resulted in Patient 1 receiving a tube feeding into the right lung. This			

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	failure is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1(c). This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).			

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