CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

AMENDED

POC accepted 12/24/13
1 yr

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050125	A. BUILDING _____ B. WING _____	03/26/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Regional Medical Center of San Jose	225 N Jackson Ave, San Jose, CA 95116-1603 SANTA CLARA COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident CA00299325 conducted on 2/10/12 to 3/26/12. Entity reported incident CA00299325 regarding State Monitoring/Wrong Gas was substantiated and a State deficiency was identified (see California Code of Regulations, Title 22, Section 70263(g)(2)). Inspection was limited to the specific entity reported incident investigated and does not represent the findings of a full inspection of the hospital.		CALIFORNIA DEPARTMENT OF PUBLIC HEALTH DEC 28 2013 L & C DIVISION SAN JOSE A. Corrective Actions taken for the deficiencies identified during the [redacted]12 event: 1. Corrective Actions accomplished for this patient who had incorrect gas administered: • On [redacted]12 once it was recognized that the wrong gas (carbon dioxide – CO2) had been applied to the patient, the Registered Nurse (RN) immediately disconnected the tubing	[redacted]12

Event ID:P6IE11 12/12/2013 2:02:59PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Nancy Fore | TITLE: CQO | (X6) DATE: 12-20-13

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 7

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 90 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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	Representing the California Department of Public Health: 06780, Health Facilities Evaluator Nurse. Informed Adverse Event Notification Health and Safety Code Section 1279.1 (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 CDPH 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. Health and Safety Code, Section 1280.1(c) (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. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY. Title 22, Section 70263(g)(2) (g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher.		**(continued from page 1)** to the wrong gas and connected the tubing now to the correct gas (oxygen – O2). The patient received approximately 5 minutes exposure to the wrong gas. The patient's condition improved; was stabilized and transferred to the ICU for on-going care and treatment. 2. Corrective Actions accomplished for this patient when the healthcare team was not notified at the time of emergency include: • On [redacted]12 once it was recognized that the wrong gas (carbon dioxide – CO2) had been applied to the patient, the circulating nurse immediately disconnected the tubing to the wrong gas and connected the tubing now to the correct gas (oxygen – O2). The patient received approximately 5 minutes exposure to the wrong gas. 3. Corrective Actions accomplished for this patient when the code blue was not activated timely:	[redacted]/12

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SAN JOSE

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	Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours. (2) Medications and treatments shall be administered as ordered. Based on documentation and interview, nursing staff failed to administer the correct medical gas to a surgery patient. Patient 1 was administered carbon dioxide gas for ventilation (assisted breathing), instead of oxygen as ordered by the physician. The nurse obtained the wrong medical gas cylinder and connected carbon dioxide gas to the patient's ventilation tubing. Failure of the patient to receive oxygen as ordered caused the patient to become hypoxic (without oxygen) which required emergency medical treatment for stabilization. The patient suffered significant medical complications, including neurological damage, as a result of the incident. Findings: A review of Patient 1's medical record on [redacted]12 indicated the 68 year old patient was assessed for complaints of chest pain and epigastric (stomach) pain at another hospital on [redacted]12. She was transferred to this hospital for treatment and underwent an immediate surgical procedure to determine an accurate diagnosis.		(continued from page 2) • Immediately upon recognition of a change in patient status, the anesthesiologist ordered chest compressions and ACLS protocol to be put into place in the OR suite. • An internal code blue within the OR was called. • Immediately upon recognition that there was not house-wide response (20 seconds), a code was called to the main hospital operator. The patient did have ACLS and CPR initiated by the team in the OR, which was lead by the anesthesiologist present. There was no delay in response to the patient by the OR team. B/C. Actions taken to reduce the risk of other patients potentially affected by the same deficient practice and measures put into place to ensure the deficient practice does not recur: 1. Changes made to eliminate the risk to other patients who might receive the incorrect gas: • Elimination of the portable CO2 cylinder in operating room (OR) #5 on 2/19/12.	[redacted]12 2/19/12

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	Further review revealed that Patient 1 arrived in the emergency room by ambulance on [redacted]12 at 9:30 p.m., she was hemodynamically stable (stable circulation/blood pressure), alert, awake, and oriented. She was taken to surgery at 11:30 p.m. on [redacted]12 for a transesophageal echo probe (a specialized probe containing an ultrasound transducer at its tip passed into the patient's esophagus, which allows image and Doppler evaluation which can be recorded) to determine if surgery was needed. The procedure results indicated cardiac surgery was not required. Because the patient was under general anesthesia (drug induced loss of consciousness during which patients are not arousable, and ventilatory and cardiovascular functions may be impaired), Patient 1 was prepared for transfer to the Intensive Care Unit (ICU). Patient 1 was not able to breathe without assistance and the anesthesiologist ordered the administration of oxygen to ventilate the patient while being transferred to the ICU. Continued review of the patient chart indicated at approximately 12:05 a.m. on [redacted]12 during preparation for transfer from the operating room to the intensive care unit Patient 1's condition deteriorated. Per a physician consultation report dated [redacted]12 at 1:13 p.m., Patient 1 developed bradycardia (slow heart rate), hypotension (low blood pressure) and eventually asystole (no heart rate). She was resuscitated but remained in severe shock with hypotension and tachycardia (high heart rate) on multiple pressors (cardiac medications). She was transferred to the ICU and was		**(continued from page 3)** • CO_2 gas is now delivered through a plumbed line attached to the centralized gas storage system via a boom from the ceiling. • All components of the CO_2 delivery system are clearly labeled. Additionally, the regulator and flow meter have internal identification from the manufacturer. — 2/19/12 • All clinical OR staff have been educated on the new CO_2 delivery system. — 3/5/12 2. Changes made to reduce the risk of other patients when the healthcare team is not notified at the time of the emergency: • The two RNs involved with this event were suspended pending the conclusion of the investigation. — 2/10/12 • At the conclusion of the investigation, appropriate disciplinary actions were taken with regards to the RNs involved in the event. — 3/16/12 • Re-education was provided to all eligible OR and RT staff on 3/5/12 regarding the Chain of Command and Sentinel Event Policies. Competency verification was completed by 4/12/12. — 3/5/12, 4/12/12	

Nancy Fox CQO 12-20-13

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	unresponsive, on a ventilator (machine that provides continuous ventilation) with severe postanoxic encephalopathy (brain damage from lack of oxygen). On [redacted]12 at approximately 4:00 p.m. an interview was conducted with the hospital risk manager regarding Patient 1's care in the operating room. The interview revealed that a nurse (Nurse B) inadvertently connected a cylinder of carbon dioxide gas to tubing that was supposed to be connected to oxygen. On 2/14/12 at 2:30 p.m. an interview with Nurse B was conducted. Nurse B stated he was called for assistance by Nurse A to transfer Patient 1 to ICU. While preparing Patient 1 for transfer, Nurse B stated he was asked to get an oxygen cylinder. Nurse B stated he retrieved what appeared to be an oxygen cylinder, connected and administered Patient 1 the gas in the tank. Patient 1's vital signs became unstable and a code blue was called (request for medical emergency assistance). During the code blue it was noted the tank he (Nurse B) had retrieve for Patient 1's use was not an oxygen tank but a carbon dioxide tank. On 3/1/12 two Respiratory Therapists (RT1 and RT 2) were interviewed. RT 1 stated she was manually ventilating Patient 1 during the code blue, and was relieved from the Ambu bag (self-inflating bag used to provide manual positive pressure ventilation to the patient) by the charge respiratory therapist (RT 2). She heard RT 2 state the tank was cold, and not green [the color of medical oxygen gas tanks].		(continued from page 4) • All OR and RT staff were Required to read the learning Module entitled Silence Kills. Competency verification was compelted by quiz by 4/12/12. • 2012 Organization-wide Culture of Safety Survey was completed by 4/12/12. Survey data will be analyzed with appropriate actions developed. • Instituted a "Patient Safety Hot Line" for staff to report patient safety concerns more rapidly and readily. The "hot line" is not in lieu of completing an occurrence report, however, an additional option for employees to report concerns. Posters advertising the "hot line" have been placed in the operating room. • An internal comprehensive Operating Room Assessment was completed on 4/2/12. Actions taken as a result of the assessment findings related to culture of safety include: charge nurses attended classes which included education on crucial	4/12/12 4/12/12 4/12/12 4/12/12

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	RT 1 said she went to check the tank with Nurse A and noted it was not oxygen. Nurse A pulled the tubing from the tank. She further stated she told the anesthesiologist to connect the tubing to the anesthesia cart as it had an oxygen source. On [redacted]12, cardiac and neurology consultations were conducted. The consultations were obtained to determine the extent of the patient's injuries due to the medical gas administration error. According to the neurological assessment, the patient's brain stem reflexes (reflexes regulated at the level of the brain stem, such as pupillary, pharyngeal, cough reflexes, and control of respirations) were preserved but due to the possibility of postanoxic seizures, a continuous EEG (electroencephalogram, to measure electrical activity of the brain) would be ordered. The cardiac assessment indicated the patient was in shock with pulmonary edema (excess fluid in the lungs) after persistent hypoxia (lack of oxygen) and exposure to carbon dioxide. The cardiac consultant concluded the patient was in critical condition, in a state of shock (organs and tissues of the body are not receiving an adequate flow of blood). Subsequent neurological consultations were conducted on [redacted]2 and [redacted]2, and were reviewed by this evaluator on 3/1/12. The [redacted]12 consultation indicated on [redacted]2 the patient had significant cognitive (mental processing) impairment, mainly due to ataxia (poor coordination and unsteadiness, a sign of cerebellar (brain) damage), recent memory loss and poor attention span. The patient had made significant		**(continued from page 5)** Conversations, lateral violence, chain of command, and responsibilities for being accountable as an extension of leadership. Charge nurse checklist was developed which emphasizes accountability and increased communication. Consultative Team Evaluation in OR will commence in May 2012. • New employee hospital orientation presentation has been updated with an increased focus on Patient Safety / Culture. • Posters related to "Speak Up" have been placed in the operating room and Respiratory Therapy Department.	May 2012 4/12/12 3/5/12

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	improvement in her neurological condition since [redacted]12, and was expected to continue to improve. Patient 1 was discharged from the hospital to a rehabilitation center on [redacted]2. Nursing staff's administration of the wrong medical gas to the patient, and the resultant failure to implement the anesthesiologist's order for administration of oxygen during transport has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of the California 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).		(continued from page 6) 3. Corrective actions taken to identify other patients who might be affected when code blue is not activated timely: • A review of the organizations' Resuscitation Policy was conducted. • It was determined that the policy was current with regulations but inconsistently followed. • The circulating nurse failed to realize that there was not sufficient staff present in the OR to assist with the code in this after-hour case. She should have paged the code to the operator immediately instead of calling an internal code. • Education was provided to the OR staff regarding when to activate house-wide code blue response team 3/13/12. D. Monitoring 1. Monitoring for incorrect gas administered: • All Clinical OR staff were educated on the new CO2 delivery system on 3/5/12. • Competency was verified with a post education quiz score of greater than 90%.	2/19/12 3/13/12 3/5/12 3/5/12

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	Regional Medical Center of San Jose		225 N. Jackson Avenue San Jose, CA 95116	
			(Continued from page 7) • Daily monitoring check of OR #5 will occur for 4 months to assure the old CO2 set-up has not been brought back to the OR. • Data will be presented to the Clinical Excellence Committee (CEC) and Board of Trustees (BOT) monthly. • Responsible Party: Director of Surgical Services.	4/26/12
			2. Monitoring when the healthcare team is not notified at the time of the emergency: • Re-education was provided to all eligible OR and RT staff on 3/5/12 regarding the Chain of Command and Sentinel Event Policies.	3/5/12
			• Competency was verified with a post education quiz score of greater than 90% by 4/12/12.	4/12/12
			• All OR and RT staff were required to read the learning module Silence Kills.	
			• Competency was verified with post education quiz score greater than 90% by 4/12/12.	4/12/12
			• Monitoring will include number of calls to the Hot Line and number of occurrence reports from the OR related to patient safety. The monitoring will continue for 4 months to determine if there is an increase in reporting. • There will be a short OR targeted patient safety survey after 4 months.	

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	Regional Medical Center of San Jose		225 N. Jackson Avenue San Jose, CA 95116	
			(Continued from page 8) • Data will be presented to the Clinical Excellence Committee (CEC) and Board of Trustees (BOT) monthly. • Responsible Party: Director of Surgical Services. 3. Monitoring when code blue is not activated timely: • Mock Code Drills are included in the annual skills day competencies. Next annual skills day validation is scheduled for 5/12/12. All clinical OR staff are required to attend the didactic, observation and clinical demonstration of skills and are verified at this training. • Mock Code drills in the OR will occur every month to ensure compliance to the code calling process. • Responsible Party: Director of Surgical Services.	5/12/12 4/12/12

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	Regional Medical Center of San Jose		225 N. Jackson Avenue San Jose, CA 95116	
			(continued from page 9) A. Corrective Action accomplished for this patient when the RN failed to administer the correct medical gas as ordered: 1. On [redacted]12 once it was recognized that the wrong medical gas (carbon dioxide – CO2) had been applied to the patient, the nurse immediately disconnected the tubing to the wrong gas and connected the tubing now to the correct medical gas (oxygen – O2). The patient received approximately 5 minutes exposure to the wrong gas. The patient's condition improved was stabilized and transferred to the ICU for on-going care and treatment. 2. The RN involved with this event was suspended pending the conclusion of the investigation. 3. At the conclusion of the investigation, appropriate disciplinary actions were taken with regards to the RN involved in this deficient practice. B/C. Actions taken to reduce the risk of this deficient practice that may affect other patients and measures put into place to ensure the deficient practice does not recur: 1. The RN involved with this event was suspended pending the conclusion of the investigation.	[redacted]12 2/10/12 3/16/12 2/10/12

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			(continued from page 10) 2. At the conclusion of the investigation, appropriate disciplinary actions were taken with regards to the RN involved in this deficient practice.	3/16/12
			3. RN was found to be non-compliant with medication administration.	
			4. Re-education was provided to all eligible OR staff, including the "5 Rights of Medication Administration" on 3/20/12.	3/20/12
			5. Competency was verified with post education quiz which was completed by 3/30/12.	3/30/12
			6. Actions were taken to decrease the risk associated with misidentification of medical gases by emphasizing correct labeling and de-emphasizing the color of the cylinder.	2/19/12
			D. Monitoring 1. Re-education was provided to all eligible OR staff, including the "5 Rights of Medication Administration" on 3/20/12.	3/20/12
			2. Competency was verified with post education quiz score of 90% which was completed by 3/30/12.	3/30/12

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			(continued from page 11) 3. Monitoring will include a minimum of 50 direct observations to assure compliance with "5 Rights of Medication Administration," per month, for 4 months. 4. Data will be presented to the Clinical Excellence Committee (CEC) and Board of Trustees (BOT) monthly. 5. Responsible Party: Director of Surgical Services.	4/26/12
			A. Corrective Actions accomplished for this patient when the RN failed to implement a policy and procedure for safe use of medical gas cylinder: 1. On [redacted]12 once it was recognized that the wrong medical gas (carbon dioxide – CO2) had been applied to the patient, the nurse immediately disconnected the tubing to the wrong gas and connected the tubing now to the correct medical gas (oxygen – O2). The patient received approximately 5 minutes exposure to the wrong gas. The patient's condition improved was stabilized and transferred to the ICU for on-going care and treatment.	[redacted]12

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			(Continued from page 12) • The registered nurse (RN) involved with this event was suspended pending the conclusion of the investigation. • At the conclusion of the investigation, appropriate disciplinary actions were taken with regards to the RN involved in this deficient practice. B/C. Actions taken to reduce the risk of this deficient practice that may affect other patients and measures put into place to ensure the deficient practice does not recur: 1. A review of the organizations current medical gas policy was conducted to determine if updates were required. It was determined that the existing policy was outdated with current literature. 2. A new Policy was developed entitled Medical Gas Cylinder Storage and Handling. The new policy emphasized a visual inspection of the gas cylinder label and eliminates identification of the cylinders by color only. 3. The policy entitled Gas Cylinder was retired due to outdated information about identification of gas cylinders based only on color.	[redacted]12 3/16/12 3/5/12 3/26/12 3/26/12

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			(Continued from page 13) 4. The new policy was presented and approved at Clinical Excellence Committee on 3/22/12 and to Medical Executive Committee on 4/2/12. 5. All eligible OR and RT staff were educated on the new policy and procedure by 4/6/12. 6. Competency verifications were completed by 4/12/12. D. Monitoring: 1. Competency verifications were completed with post education quiz score of 90% by 4/12/12. 2. Daily charge nurse rounds will include verbal questions or direct observations to assure policy compliance. There will be a minimum of 30 observations per month for 4 months. 3. Data will be presented to the Clinical Excellence Committee (CEC) and Board of Trustees (BOT) monthly. 4. Responsible Party: Director of Surgical Services.	3/22/12 4/12/12 4/6/12 4/12/12 4/12/12 4/26/12

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