

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY  
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>053305</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED  <b>11/16/2007</b>
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NAME OF PROVIDER OR SUPPLIER  <b>LUCILE SALTER PACKARD CHILDREN'S HOSP AT STANFORD</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>725 WELCH ROAD, PALO ALTO, CA 94304 SANTA CLARA COUNTY</b>
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	<p>The following reflects the findings of the California Department of Public Health during an Entity Self Reported event visit.</p> <p>For Entity Self Reported event CA00131082 regarding State Monitoring, oxygen line used for wrong gas/toxic substance, a State deficiency was identified (see California Code of Regulations, Title 22, Section 70617(a)).</p> <p>Inspection was limited to the specific Entity Self Reported event investigated and does not represent the findings of a full inspection of the hospital.</p> <p>Representing the California Department of Public Health was [REDACTED] Health Facilities Evaluator Nurse.</p> <p>The above regulation was not met as evidenced by:</p> <p><b>DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY.</b></p> <p>70617(a) Respiratory Care Service General Requirements (a) 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.</p> <p>Based on interviews, record and document review, the hospital failed to implement their policies and procedures for the storage and assembly of</p>			
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Event ID:9EQ811

5/8/2008

11:16:37AM

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	<p><b>Continued From page 1</b></p> <p>nitrogen gas used for the Nitrogen blend procedure for one patient (A). The hospital failed to ensure diagrams accurately illustrated the setup of the nitrogen gas for the ventilator.</p> <p>Patient A, a nine day old infant, had a diagnosis of Epstein's anomaly, a rare congenital defect of the heart involving the tricuspid valve which pumps blood through the heart's upper chamber. Patient A was admitted to the Neonatal Intensive Care Unit (NICU) for cardiac evaluation and treatment. The record documented he was placed on the heart transplant recipient list on 10/12/07.</p> <p>The physician documented on the History Progress Record dated 10/16/07 at 4:00 a.m. the following: The patient "returned from the catheterization (cath) lab after stent replacement... for severe Epstein's anomaly before heart transplant. Patient was stable during the procedure according to anesthesia....Tried to place patient on Nitrogen to decrease over circulation and decrease high SAT's (oxygen in the blood) but every time put on a ventilator, rapid bradycardia (low heart rate) followed by profound desaturation.... One episode of brady to 54- gave chest compressions x 3 (~ 30 seconds) until bagging (providing ventilation manually) brought HR and SAT up.... Stabilized on ventilator once Nitrogen taken out of circuit...."</p> <p>On 11/05/07 at 12:30 p.m. the respiratory therapy manager (RTM) was interviewed. He stated the Nitrogen Blend procedure is used to decrease atmospheric oxygen to decrease oxygenation to the pulmonary system and increase systemic</p>			
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	<p><b>Continued From page 2</b></p> <p>circulation. The goal is for the patient to receive 16% to 18% oxygen (O2) instead of 21%, which is received in room air.</p> <p>The RTM stated this procedure is used for heart transplant patients. The hospital uses the equipment 10 or less times a year. He stated on 10/16/07 the respiratory equipment used to blend nitrogen for Patient A was incorrectly assembled by the respiratory therapist 1 (RT 1).</p> <p>He stated the hospital had five setups for nitrogen administration and they were to be ready for use at all times. Only one could be located in the respiratory department on 10/16/07 because of new construction being done. He said the equipment used for Patient A had been disassembled; the hoses used in Nitrogen delivery were not connected before use, as per policy. The connectors to the hoses that were supposed to be noninterchangeable had been removed which allowed the hoses to be connected incorrectly.</p> <p>The Nursing Neonatal Intensive Care Flow Sheet dated 10/16/07 from 2:25 a.m. to 3:50 a.m. documented the patient was removed from the ventilator and had to be manually ventilated a total of five times when the nitrogen was added to the patient ventilator circuit. The patient's heart rated dropped as low as 62 beats per minute (normal range is 100 to 160 for a newborn). The O2 Sat dropped as low as 56 percent. The record documented the goal for the patient's O2 Sat was 75 to 85 percent.</p>			

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	<p><b>Continued From page 3</b></p> <p>The hospital policy and procedure on Nitrogen Blend documented the following: "all equipment (blender, regulators etc.- except hood or ventilator), when not at bedside, should be stored together in the department." The hospital failed to follow their policy on storage of equipment.</p> <p>The above policy also documented the equipment should include a modified blender, H- cylinder of 100% medical grade nitrogen, nitrogen tank regulator (to check pressure in tank), and 2 alarmed oxygen analyzers capable of monitoring oxygen concentrations of less than 20.9%.</p> <p>On 11/09/07 at 9:00 a.m. RT 1 who set up the nitrogen blend equipment was interviewed by telephone. She stated the following: On 10/16/07 she was told Patient A was being transferred from the cardiac cath lab in 10 minutes and would need to be on the nitrogen blend. She got the equipment from the respiratory department. The equipment had a clear plastic bag over it which is placed by the technicians to signify it is assembled and ready for use. She later discovered the bag was placed over the machine to protect it from dust during construction, but was not assembled.</p> <p>RT 1 stated when she took the plastic bag off the equipment the two hoses were hanging on the side of the machine instead of being connected to the blender. She had never set up the equipment so she had to rely on a diagram. The adaptors to connect the hoses to the blender inlets had been removed. The regulators, flowmeters and the analyzers needed for the equipment set up were</p>			
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	<p><b>Continued From page 4</b></p> <p>not in the bag used to store these items. The hospital failed to implement their policy on equipment to be available for the nitrogen blend procedure.</p> <p>RT 1 stated each time the nitrogen was used the patient immediately had significant changes so the patient was removed from the ventilator and the patient was hand bagged. RT 2 found an analyzer to use but the readings were questionable so he looked for another analyzer which could not be found until the procedure was stopped. RT 1 stated, "analyzers are hard to come by." The nitrogen was removed when RT 2 discovered the hoses to the blender had been incorrectly connected.</p> <p>RT 1 stated the diagram she used to set up the equipment was drawn backwards so she incorrectly connected the hose with the 100% nitrogen to the room air inlet side of the blender instead of the oxygen inlet. She connected the compressed air hose to the oxygen inlet side of the blender instead of the room air inlet. Instead of 100% nitrogen blended to less than 40% and 21% compressed air, the patient received 100% nitrogen and an undetermined percentage of oxygen. She stated she reported the above to the physicians and to the department manager immediately.</p> <p>The hospital policy and procedures for Nitrogen Blend documented, "diagrams depicting set ups for the ventilator...should be available with the equipment..." On 11/16/07 the Nitrogen Vent Setup diagram was reviewed. The diagram illustrated the hose from the nitrogen tank</p>			

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	<p><b>Continued From page 5</b></p> <p>connected to inlet on the left side of the blender and the hose for compressed air connected the inlet on the right side of the blender. The hospital failed to have diagrams that accurately depicted correct set ups for the nitrogen blend procedure.</p> <p>On 11/14/07 at 10:45 a.m. the NICU attending physician was interviewed by telephone. He stated he was called at home around 3:00 a.m. on 10/16/07 because the staff was having difficulty stabilizing the patient on the ventilator. After attempts to place the patient on the ventilator were unsuccessful RT 2 stated, "I am not sure the nitrogen set up is correct." RT 1 pulled the nitrogen out and the patient was able to be stabilized with oxygen Sats in the mid 80's. When asked if the above incident had a potential for harm the physician stated, "potentially it could have been a disaster, a catastrophe."</p> <p>On 11/14/07 at 12 noon RT 2 was interviewed by telephone. He stated on 10/16/07 he was called to assist RT 1. He stated the equipment for the nitrogen set up was in "pieces." There was no analyzer with the equipment so he found one in another location. The analyzer when connected showed oxygen readings in the teens and dropping to zero.</p> <p>RT 2 stated he left to find a second analyzer and when it was connected it gave the same readings. He then realized the set up must be wrong so he removed the nitrogen and notified the physician who was at the bedside.</p>			
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	<p><b>Continued From page 6</b></p> <p>On 11/16/07 at 12 noon a licensed nurse (LN) was interviewed by telephone. She stated she was at Patient A's bedside on 10/16/07 during the time the nitrogen blend procedure was administered. She stated the patient was stable on the "conventional ventilator" but became bradycardic (slow heart rate) and his oxygen Sat's dropped when he was placed on the ventilator with nitrogen added. The patient needed to be taken off the ventilator with nitrogen and hand bagged "multiple times." When the nitrogen was removed and the patient was placed back on the "conventional ventilator" he appeared to stabilize.</p>			
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