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
	050077	A. BUILDING _____ B. WING _____	09/10/2008

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SCRIPPS MERCY HOSPITAL	4077 FIFTH AVENUE, SAN DIEGO, CA 92103 SAN DIEGO COUNTY

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	The following reflects the findings of the California Department of Public Health during the investigation of an entity reported adverse event. Entity reported incident: 162209 Category: State Monitoring Sub-Category: Use of device other than as intended Representing the California Department of Public Health: [redacted] The inspection was limited to the specific entity reported adverse event and does not represent the findings of a full inspection of the hospital. 70619(b)(3). Respiratory Care Service Staff. (b) The day-to-day operation of the service shall be under the immediate supervision of a technical director who shall be a respiratory therapist, respiratory therapy technician, cardiopulmonary technologist or a registered nurse with specialized training and/or advanced experience in respiratory care, who shall be responsible for: (3) Supervising the maintenance of equipment. 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		RECEIVED DEC 24 2008 LICENSING AND CERTIFICATION SAN DIEGO DISTRICT OFFICE SOUTH CT 12/24/08	

Event ID: YI8311 12/9/2008 9:05:44AM

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Kathy Seney | Director Risk Management | 12-23-08

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	Continued From page 1 and medical staff where such is appropriate. 70215(a)(1). Planning and Implementing Patient Care (a) A registered nurse shall directly provide: (1) Ongoing patient assessment as defined in the Business and Professional Code, Section 2725(d). Such assessments shall be performed, and findings documented in the patient's medical record, for each shift, and upon receipt of the patient when he/she is transferred to another patient care area. Based on observation, interviews and record review, the facility failed to maintain respiratory equipment in accordance with its own policy and procedure, and manufacturer's guidelines and recommendations. The facility also failed to ensure that faulty or broken respiratory equipment was not used by staff to provide ventilatory support to Patient 1, a trauma patient with a brain injury. In addition, the facility failed to ensure that assessments of Patient 1's respiratory status were performed by a licensed nurse and a respiratory therapist, at critical points during the transport of the patient from the critical care unit to a portable (located outside of the facility) MRI (Magnetic Resonance Imaging) unit. As a result, after Patient 1 was administered Vecuronium (a drug which causes paralysis to include breathing muscles) and Versed (a drug that causes sedation) to facilitate the MRI procedure, the patient experienced a respiratory and cardiac arrest. It was discovered that a faulty portable ventilator (a machine designed to mechanically move breathable air into and out of		Scripps Mercy Hospital acknowledges its responsibility to self-report certain patient care events. Concerns related to Patient 1's care were self-reported by the hospital to CDPH office on September 3, 2008. In response to the resulting Statement of Deficiencies, the following Plan of Correction is submitted. 1. In order to ensure that respiratory equipment is maintainted in accordance with manufacturer's guidelines and hospital policy Respiratory -Equipment Control, MER-RT-PC-3567, the following actions have been taken: 1.1: Policy Respiratory-Equipment Control MER-RT-PC-3567. (attachment A) has been amended to reflect the practice of cleaning, inspecting, testing and logging equipment between uses. The ParaPac Setup Checklist (attachment B) has been implemented to record the cleaning, inspection and testing. Responsible person: Respiratory Therapy Manager Monitor: The ParaPac Setup Checklist matched against the Ventilated Patient Transport Flowsheet to assure that 100% of transport ventilators used are being cleaned/inspected/tested as per policy. Results will be reported to the Quality Assurance/Performance Improvement Committee.	9/12/08 9/22/08 – 10/22/08

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	Continued From page 2 the lungs, to provide mechanism of breathing for a patient who is physically unable to breathe, or breathing insufficiently) was not set correctly in order to deliver breaths to the now paralyzed patient. Continued implementation of the above practices by the facility was likely to place other patients who were dependent on transport ventilators in a situation of immediate jeopardy with a potential to cause serious injury or death. Findings: The facility self reported an adverse event, dated 9/3/08, which documented that: "RT (respiratory therapist) staff knew that they were using a faulty vent (ventilator) but they chose to use it anyway." On 9/4/08 at 2:05 P.M., an investigation based on the facility's self-reported adverse event was initiated. On 9/4/08 at 2:30 P.M., upon arrival to the Intensive Care Unit (ICU), Patient 1 was observed in bed with his eyes closed. The patient had a tracheostomy (a surgical procedure in the patient's trachea to open a direct airway through an incision) with the tube coming out of his throat that was connected to a ventilator. The patient's neck was supported with a neck brace. The patient was motionless. Two of the patient's family members were at the bedside. When asked how the patient was, one of the patient's family member stated, "Since the cardiac arrest, not good." An interview with two of the patient's family members was requested and granted. A private interview with the patient's family		2. In order to ensure that faulty or broken equipment will not be used by staff, the following actions have been taken: 2.1 Equipment Safety Stand Down (attachment C) developed for mandatory education of all hospital staff related to inspecting equipment and the process for taking equipment out of service. Responsible person: Safety Committee Chairperson Audit: Safety Sweeps conducted to validate staff competency and inspect equipment. Results will be reported to the Safety Committee. 3. To ensure that assessments of respiratory status are performed by a licensed nurse and a respiratory therapist at critical points during transport of a patient outside of the critical care unit to a portable unit, the following actions have been taken: 3.1 The policy Transport of Monitored and Ventilated Patients, Guidelines for Interdepartment Transport-MER-FW-PC-3501 (attachment D) was revised to reflect specific assessment requirements during intra-hospital transport of a critical care patient on a ventilator to include continuous end-tidal C02 monitoring. Responsible person: Administrative Director, ICU 3.2 The policy End Tidal C02 Monitoring MER-FW-PC-3931 (attachment E) was revised to describe the use of End Tidal C02 monitoring during intra-hospital transport Responsible person: Administrative Director, ICU	9/8/08-10/1/08 9/15/08 – 10/3/08 9/8/08 9/8/08

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	Continued From page 3 was conducted in one of the waiting rooms close to the ICU. According to a family member, the facility's Director of Risk Management and Patient Relations informed them that the facility's investigation of the incident revealed that Patient 1's ventilator had not been turned on. The patient's family member stated that prior to the incident on 9/1/08, the patient was able to squeeze their hands and move his extremities but since the incident, the patient had not moved. An interview with licensed nurse (LN) A was conducted on 9/4/08 at 3:15 P.M. She stated that Patient 1 would open his eyes to painful stimuli and would cough when suctioned. However, she stated that the patient had no motor function and could not move on his own. On 9/4/08 at 3:20 P.M., Patient 1's medical record was reviewed. Patient 1 was admitted to the facility on 8/21/08 with diagnoses that included subarachnoid hemorrhage (bleeding in the area between the brain and the thin tissues that cover the brain) per the History and Physical, dated 8/22/08. A review of the Trauma Team ICU notation, dated 9/1/08 timed at 6:50 A.M., indicated that Patient 1 was able to wiggle his toes bilaterally. A physician's progress notes, dated 9/1/08 timed at 9:50 A.M., indicated that the patient followed with his eyes and occasionally followed command. A physician's order, dated 9/1/08, indicated that an order was written at 1:23 P.M. for "Vecuronium 10 mg (milligrams) IV (intravenous) x 1 for MRI; Versed		3.3 The policy Pharmacologically Paralyzed Patient Care MER-FW-PC-3156 (attachment F) was revised and reviewed by appropriate physician supervisory committees to affirm our practice of RN administration of a paralytic to an airway protected patient. Responsible person: Administrative Director, Critical Care 3.4 The policy Respiratory -Ventilation During Transport MER-RP-PC-3927 (attachment G) was developed and approved to provide guidelines for the safe and effective monitoring of ventilator dependent patients during intra-hospital transport. Responsible person: Respiratory Therapy Manager 3.5 The Ventilated Patient Transport Flowsheet (attachment H) was developed to record ventilator status upon set-up and to record end tidal C02 readings, breath sounds and respiratory rate. Responsible person: Respiratory Therapy Manager Monitor: A chart audit of all ventilated patient intra-hospital transport care to ensure that end-tidal C02 was in use, ventilatory status was assessed and Ventilated Patient Transport Flowsheet was in use. Results will be reported to the Quality Assurance/Performance Improvement Committee.	9/8/08 9/18/08 9/18/08 9/8/08 – 10/10/08

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	Continued From page 4 2 mg IV for MRI may repeat x 1." On 9/4/08 at 3:25 P.M., an interview with Physician A was conducted. According to Physician A, on 9/1/08 (no time given), a "code blue" (generally used to indicate a patient requiring immediate resuscitation, most often as the result of a cardiac arrest) was called to the MRI trailer. He stated that when he got to the MRI trailer, CPR (cardiopulmonary resuscitation) was already in progress and Patient 1 was later taken back to the ICU. He stated that the RT told him the transport ventilator was "off." According to Physician A, he looked at the transport ventilator and noticed that the "on and off" knob was missing. He stated that he told the patient's family that the ventilator was probably the problem. According to Physician A, prior to the incident, Patient 1 was able to move all extremities purposefully. However, after the incident, no purposeful movement was observed. On 9/4/08 at 5:00 P.M., the biomedical lead staff arrived for interview with the transport ventilator in question. The transport ventilator had two missing knobs, one was the "on and off" knob and the other was the "pressure relief" knob. A sticker on top of the ventilator indicated that it was last maintained on 4/2008 and was due on 10/2008. According to the biomedical lead staff, the transport ventilators were maintained no more frequently than every six months. He stated that the transport ventilators were pneumatic ventilators which meant that it was operated with oxygen. He stated that when the transport ventilator was connected to an oxygen tank, even if the "on and off" knob was set on the			

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	Continued From page 5 "off" position, the ventilator was "on." However, it would be operating on demand mode (provided partial ventilatory support for patients who were able to breathe spontaneously). Therefore, a patient who was not able to breathe spontaneously due to paralytic medication would not be able to breathe. On 9/5/08 at 9:35 A.M., an interview with Physician B was conducted. He stated that according to the Neurologist that had been following Patient 1, there had been a "significant insult" to the patient's neurological status after the incident on 9/1/08. On 9/5/08 at 9:45 A.M., an interview with Physician C was conducted. He stated that there were no changes observed on Patient 1 since the incident on 9/1/08. On 9/5/08 at 10:13 A.M., an interview with LN B, who was Patient 1's assigned nurse on the day of the incident, was conducted. She stated that prior to the incident; Patient 1 was able to squeeze his hands and was able to move all extremities. She also stated that the patient was able to nod his head but the appropriateness was questionable. On the day of the incident, she stated that the RT brought the transport ventilator to the bedside. She stated that she saw him flip a switch and place the patient on the transport ventilator. She stated that the transport ventilator was placed in between the patient's legs. She stated that she watched the monitor the whole time during the transport but did not record the vital signs. LN B stated that when they reached the MRI unit, the MRI technician transferred the patient to a monitor that was			

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	Continued From page 6 compatible with the MRI while LN B administered Versed and Vecuronium to the patient. LN B stated that the patient's blood pressure was 106/52 and the oxygen saturation (a relative measure of the amount of oxygen that is dissolved or carried in a given medium) was 98% after the sedative and paralytic drugs were given. However, LN B did not indicate that the patient's respiratory rate or chest excursions (one complete movement of expansion and contraction of the lungs and their membranes as in breathing) were assessed, to ensure the patient was breathing nor was there any documentation of the patient's respiratory status when the patient was first placed on a transport ventilator, during the transport, and after the administration of the drugs. LN B stated that after the patient was set-up for the procedure, the MRI technician started the scan while she and the RT watched the portable monitor. She stated that there was no EKG (electrocardiogram - a noninvasive transthoracic graphic produced by an electrocardiograph, which records the electrical activity of the heart over time) activity and no wave form on the oxygen saturation reading. According to LN B, the scan was stopped and the patient was assessed. She stated the patient looked dusky and it did not look like the patient was breathing. She stated that the monitor in the MRI unit only measured oxygen saturation and not respiratory rates. She stated that code blue was called and the patient was eventually transferred back to the ICU. LN B stated that the RT told her the ventilator was on the "off" position. On 9/5/08 at 11:25 A.M., an interview with the MRI			

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	Continued From page 7 technician was conducted. He stated that Patient 1 arrived at the MRI unit between 2:15 P.M. and 2:30 P.M. He stated that he placed the patient on the MRI compatible monitor. He stated that a remote EKG and oxygen saturation monitor was placed on the patient. He stated that he started the "scout scan" (a preliminary scan before the actual scan) at 2:36 P.M. which ran for about 32 seconds until the RT told him that there was no oxygen saturation reading on the monitor. The scan was stopped and the patient was assessed. He stated that he told the RT that it did not look like the patient was breathing. The MRI technician stated that he and the RT took the patient outside and the RT started bagging (to provide ventilation to a patient who is not breathing or who is breathing inadequately by using a hand-held bag valve mask) on the patient. The licensed nurse called code blue and CPR was started. On 9/5/08 at 12:05 P.M., an interview with the RT was conducted. On the day of the incident, he stated that an RT Lead brought the transport ventilator to Patient 1's bedside. He stated that when he came back from lunch, a transport ventilator was already at the patient's bedside. He stated that he placed the patient on the transport ventilator. When shown the transport ventilator in question, he confirmed that there were two knobs missing. He stated that one of the knobs was the "on and off" knob and the other was the "pressure relief" knob. He confirmed that without the "on and off" knob, it was difficult to see whether the transport ventilator was on the "on" or "off" position. When asked about the "pressure relief" knob, he			

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	Continued From page 8 stated that he did not look at the setting because it was always set at "60". According to him, he had used the transport ventilator a number of times, on other patients, with the knobs missing. During transport, he stated that he could not see if the patient had chest excursions because the patient was covered with a sheet. He stated that the patient was moved to the scanner and they all went outside. The RT did not indicate that he assessed the patient's ventilation status at any time while the patient was being placed in the scanner nor before he left the procedure room. He stated that he looked at the monitor but it did not show any reading. He stated that when he went inside, he noticed that the transport ventilator was in the "off" position. He stated that he turned the transport ventilator on the "on" position but did not see any improvement. He stated that the patient did not have chest excursions. He stated that he bagged the patient and "code blue" was called. According to the RT, after a regular ventilator was used on a patient, the ventilator would be taken to the RT department to be cleaned and it would go through a checklist. He stated that a green sticker would be placed on the machine to indicate that it had been cleaned, reassembled, and that a test run had been performed. However, with transport ventilators, he stated that after each use, the ventilator would be cleaned, disinfected and placed back on a shelf in the ICU. On 9/5/08 at 2:55 P.M., an interview with the RT Manager was conducted. He stated that staff were told during orientation that if a machine was broken, biomedical should be notified.			

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	Continued From page 9 On 9/5/08 at 3:00 P.M., an interview with the Clinical Respiratory Specialist/Educator was conducted. He stated that the transport ventilators functionality should be checked before it was used. He stated that there was no policy in place regarding checking the functionality of the transport ventilators. He stated that before the transport ventilator was connected to the patient, the pressure should be checked on the gauge. He also stated that while the patient was connected to the transport ventilator, the RT should listen to the patient's breath sounds, watch for chest excursions and check the vital signs. He stated that if something was not right, RT should contact biomedical. When asked regarding the incident, he stated that the RT should have checked the patient's respiratory rate and chest excursions after the paralytic drug was administered. He also stated that an oxygen saturation of 98% did not mean that the patient was getting adequate ventilation. When asked regarding the missing "pressure relief" knob on the transport ventilator in question, he stated that "pressure relief" should be adjusted depending on each patient's needs. This contradicted the statement that the RT disclosed during the interview when he stated that the "pressure relief" knob was always set at "60". On 9/9/08 at 11:00 A.M., an interview with the Clinical Respiratory Specialist/Educator was conducted. He stated that the facility did not have a written policy regarding assessments that the RT would conduct on a ventilated patient. He stated that it was the facility's standard of practice to			

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(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
	Continued From page 10 conduct physical assessments. The facility's policies and procedures were reviewed on 9/9/08 at 3:00 P.M. According to the facility's policy and procedure titled Medical Equipment, Operator Responsibility for Inspection, Maintenance and Obtaining Repairs, "1. In order to assure proper operation of medical equipment, certain operator procedures are established. These include: b. Visual inspection for integrity of cords, switches, displays c. Operational checks according to manufacturers recommendations d. Basic troubleshooting of problems." Per the same policy, "For all repairs fill out a work order, attach it to the broken equipment and call BIOMED (biomedical). If available, work orders are also accessible on line.... Take the broken device out of service." A review of the User's manual for the transport ventilator indicated that "The following steps are recommended to be taken after every use: (i) Carefully inspect the complete system and make note of what actions should be taken. In particular check for damage to hoses or masks, contamination of any component, evidence of any part having been subjected to excessive force, missing parts and gas cylinder contents." There were 13 steps listed in the User's Manual when conducting functional checks on the transport ventilators. This policy and procedure and User's Manual recommendations were not implemented as written when the RT Lead and the RT decided to use a faulty transport ventilator. In addition, there was no evidence that the faulty transport ventilator was			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050077	A. BUILDING _____ B. WING _____	09/10/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SCRIPPS MERCY HOSPITAL	4077 FIFTH AVENUE, SAN DIEGO, CA 92103 SAN DIEGO COUNTY

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	Continued From page 11 reported to biomedical when it was first identified as faulty. There was no evidence that the RT conducted a functional check on the transport ventilator when Patient 1 was first switched from a regular ventilator to a transport ventilator. A review of the facility's policy and procedure titled Mechanical Ventilation indicated that, "A check should be performed following any change in ventilation settings... Patient-ventilator system checks must include patient information and observations indicative of the ventilator's settings at the time of the check. Observations should include but are not limited to: .....21. Documentation of the patient's response to mechanical ventilation at the time of the check. Clinical observations should include but are not limited to an evaluation of breath sounds; spontaneous respiratory rate, volume, and pattern; and apparent stability and position of the tube..." This policy was not implemented when there was no evidence that the RT assessed Patient 1's respiratory status when the patient was first switched from a regular ventilator to a transport ventilator. In addition, there was no evidence that the RT and the licensed nurse assessed the patient's ventilatory status after the patient was given a paralytic and a sedative drug. On 9/10/08 at 8:30 A.M., an Immediate Jeopardy was called related to the maintenance of respiratory equipment and patient assessment. An acceptable plan of correction was in place and the Immediate Jeopardy was abated that same day. The COE (Chief Operating Executive), CNE (Chief Nurse Executive), Director of Patient Safety,			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

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.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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	Continued From page 12 Administrative Director of Critical Care, Administrative Director of Quality and Director of Risk Management were present.			

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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