PRINTED: 11/09/2009
FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA030000149	A. BUILDING _____ B. WING _____	C 11/05/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SUTTER DAVIS HOSPITAL	2000 SUTTER PLACE DAVIS, CA 95616

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E 000	Initial Comments The following reflects the findings of the California Department of Public Health during an investigation of an entity self report (ESR) #CA00145077. On 3/24/09 an unannounced visit was made to the facility to investigate the ESR. Subsequent site visits were made on 3/26/09, 5/22/09 and 8/20/09. Inspection was limited to the specific complaint (s) investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: [redacted] Medical Consultant Commonly used abbreviations in the survey report included: CT - computerized tomography, a type of radiographic imaging test RN - registered nurse RT - respiratory therapist ICU - intensive care unit mg - milligram ml - millilliter	E 000		
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.	E 448		

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: QM manager — (X6) DATE: 12/7/09

STATE FORM 6899 S5XD11 If continuation sheet 1 of 11

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E 448	Continued From page 1 This Statute is not met as evidenced by: Based on staff interviews, document and medical record reviews, the hospital failed to ensure that written policies and procedures were developed and implemented to ensure the safe provision of contrast CT (computerized tomography) procedures for 1 of 1 patient record reviewed (Patient A). Findings: 1. Review of the medical record for Patient A on 3/24/09 indicated that Patient A presented to the hospital for acute decompensation of multiple, serious, chronic, and complex upper and lower airway diseases on [redacted]. Patient A was admitted to the intensive care unit (ICU), treated with antibiotics, steroid and bronchodilator medications, and oxygen. Patient A complained of neck pain and swelling. Patient A's treating physician ordered a contrast CT scan of both the chest and neck. Premedication with an antihistamine medication and additional steroid medication was ordered for Patient A's history of iodine allergy (Iodine is contained in CT constrast material). The premedications were administered in the 12 hours prior to the contrast CT tests. During the contrast CT studies, Patient A became medically unstable and required resuscitation. Attempts to ventilate Patient A were unsuccessful and Patient A expired approximately two hours after the instability was identified. Review of the medical record for Patient A indicated that Patient A was oxygen dependent and had "acute on chronic" diseases of both the upper and lower airways. The physician history and physical examination report (H&P) described a history of chronic obstructive lung disease plus restrictive lung disease secondary to a severely	E 448	CORRECTIVE ACTION TAKEN: 1. CT policy and corresponding forms and documents have been revised to ensure patient safety is assessed for contrast studies. – See IJ response for details. 2. During after hours, if ED physician is unavailable to supervise, then the on-call Anesthesiologist will be notified and will have to be immediately available for the test to be performed. 3. Contrast Worksheet is now a permanent part of the medical record. PERSON RESPONSIBLE: Jo-Lisa Miller, DI Manager DATES OF COMPLETION: Approved by the MEC on 11/18/09; Will go to the MPC on 12/3/09; Will go to the Board of Trustees on 12/14/09. MONITORING PROCESS: Pharmacy to conduct IV Contrast audits on a quarterly basis. A random sample of 30 charts will be reviewed. The results will be presented to the Quality & Patient Safety Council and the MEC. Target Compliance: 90% . Monitoring will be done until compliance target is met for 4 consecutive quarters.	

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E 448	Continued From page 2 elevated left diaphragm and various levels of collapse of both left upper and lower lung lobes and pulmonary hypertension (chest CT findings of [redacted]). Patient A was previously hospitalized for respiratory failure in [redacted]. The patient's arterial blood gas during that hospitalization measured the partial pressure of carbon dioxide in the blood (pCO2) as 89 millimeters of mercury (mmHg) at admission, and as 77 mmHg at discharge (Improved). The only other pCO2 measurement in the records after that was from [redacted] at 69 mmHg. (Normal pCO2 is 35-45 mmHg; higher levels indicate CO2 retention and poor exchange of gases between the blood and lungs.) Patient A presented to the emergency department on [redacted]8 with acute respiratory decompensation in the preceding two weeks. The blood gas measurement indicated respiratory failure with the pCO2 at 126 mmHg. Regarding the upper airway, the H&P described Patient A to have a "very short neck" with extremely decreased breath sounds, a history of cleft lip repair, and imaging tests in [redacted] and [redacted] that indicated a large thyroid goiter and nodules in the neck due to hyperthyroid disease. The attending physician progress notes written on [redacted]8 and [redacted] documented "known large goiter," cleft lip repair, saddle nose deformity, barrel chest, elevated left hemi-diaphragm with a shift of the mediastinum (mid chest structure that contains the major air passages to the lung air sacs) to the right with complete collapse of the left lower lung lobe and moderate air space disease in the right lower lung lobe, all features that can compromise ventilation. In the first two days of hospitalization the blood gas pCO2 measurement remained greater than 120 mmHg.	E 448		

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E 448	Continued From page 3 On [redacted] the physician progress note indicated Patient A complained of neck pain for which neck and chest CT scans (with contrast) were ordered. A pre-printed "Patient Prescription" for Prednisone (steroid) and Benadryl (antihistamine) was filed as a pre-procedure order from the "Medical Director for Diagnostic Imaging" for the contrast CT scan due to "history of reaction to iodine based intravenous contrast agents in the past." The order was noted by nursing staff on [redacted] at [redacted] On [redacted] a[redacted] nursing notes documented "Transport to CT via bed on monitor [with oxygen]." In an interview with the diagnostic imaging manager (DIM) on 3/24/09 at 9:30 a.m., the DIM indicated she had participated in a review of the radiology care preceding Patient A's death in the CT procedure room or[redacted] The DIM stated that on [redacted] a staff member notified an emergency department (ED) physician that a CT scan was going to be performed next door. Although the ED physician was expected to "supervise" the CT procedure, no physician was actually present in the location where the procedure was performed. The DIM stated that only a nurse and an imaging technician were in attendance with Patient A for the CT studies. The DIM went on to explain that CT technicians were expected to record specific details for each procedure on a worksheet, but the DIM could not locate any CT tech notes or records in Patient A's medical record. The DIM had learned that approximately half of the calculated contrast material (35 milliliters) was injected into Patient A, Patient A's arms were positioned above her head while she was lying flat on the scanner table, and the chest CT was completed over approximately 3 to 5 minutes, though no technician notes were	E 448		

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E 448	Continued From page 4 found to verify that. A preliminary and final chest CT report was in Patient A's medical record consistent with a completed study. The DIM further explained that toward the end of the first CT procedure, the nurse observed Patient A having some type of distress, the nurse and technician attempted to reposition the arms but Patient A's oxygen level and blood pressure fell, and a Code Blue (emergency) was called. The DIM verified that there were no vital sign measurements or nursing monitoring notes recorded during the CT procedure (or after leaving the ICU at 7:15 a.m.) until close to 8 a.m. when the Code Blue was initiated. The DIM indicated the Imaging Department did not have specific policies to address the management of patients with anatomical deformities that compromise the airway, or other conditions that compromise the airway, when performing procedures in the radiology (CT) suite. In an interview with an imaging technician (Tech 4) on 5/22/09 at 1:50 p.m., Tech 4 indicated that a physician was not required to be present during imaging procedures that involved the administration of contrast material. Tech 4 expected an emergency room physician to be available if there were problems. Tech 4 was not aware that only one physician was on duty in the emergency room on [redacted] when Patient A underwent a contrast procedure, and that physician documented in Patient A's record periodic departures to tend to other patients in the emergency room. Tech 4 had no specialized training in airway assessment, positioning, or ventilation techniques. Tech 4 relied on the presence of a nurse to recognize if a patient was requiring medical attention, as assessment was beyond her scope of practice. Tech 4 believed the premedications for patients	E 448		

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E 448	Continued From page 5 with a history of iodine allergy worked very well, and had never witnessed a serious contrast reaction when patients were premedicated. Tech 4 stated that a question had been added to the "IV Contrast Worksheet" used by the technicians to determine if a patient's airway would be at risk in the supine position (laying flat on the back). Tech 4 was not aware of any policies and procedures to guide the positioning of patients with airway difficulties, and had had no trainings on the revised worksheet. In an interview with Physician 15 on 8/20/09 at 9:45 a.m., Physician 15 stated that radiologists were not physically present for all contrast procedures. Even when a radiologist was on site, the radiologist did not evaluate the medical conditions or stability of the patient prior to a procedure. The radiologist relied on a nurse to monitor vital signs. Physician 15 acknowledged that a registered nurse was not expected to recognize the features of a reaction to contrast material. A registered nurse was not expected to know how to treat a contrast reaction. A registered nurse was not expected to recognize how the procedure positioning of a patient with very complex airway conditions could compromise ventilation. Physician 15 indicated there were no radiology department policies and procedures dedicated to the safe provision of high risk procedures, such as the administration of contrast material. Physician 15 indicated that no discussions about preparing high risk patients for imaging procedures in the radiology suite had ensued following the death of Patient A, though the crash carts had become standardized and were now regularly stocked. The American College of Radiology Manual on Contrast Media pages 23-27, revised 9/09/08,	E 448		

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E 448	Continued From page 6 was reviewed on 3/25/09. On pages 23-27 the adverse effects of iodinated contrast media were described. Life-threatening reactions were noted to appear identical to an anaphylactic reaction (allergy-triggered swelling of the airway and body). Certain patients were at increased risk for adverse events, including patients with prior reaction to contrast injection and patients with thyrotoxicosis (elevated thyroid hormone levels). Severe reactions included very rapid cardiopulmonary collapse, bronchospasm (narrowing of large airway), laryngeal edema (swelling and narrowing of airway), seizure, hypotension (low blood pressure), and pulmonary edema (swelling and fluid accumulation in the lungs).	E 448		
E1950	T22 DIV5 CH1 ART7-70707(b)(5) 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: (5) Receive as much information about any proposed treatment or procedure as the patient may need in order to give informed consent or to refuse this course of treatment. Except in emergencies, this information shall include a description of the procedure or treatment, the medically significant risks involved in this treatment, alternate courses of treatment or nontreatment and the risks involved in each and to know the name of the person who will carry out the procedure or treatment.	E1950		

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E1950	Continued From page 7 This Statute is not met as evidenced by: Based on staff interviews, medical record and document reviews, the hospital failed to ensure that a properly executed informed consent was obtained and documented for patients undergoing high risk radiographic procedures that utilized the administration of contrast material, in accordance with medical staff policies. Findings: Review on 3/25/09 of medical staff policy and procedure 4.3 titled, "Consents," revised 7/08, identified a definition for invasive procedures as "procedures involving puncture or incision of the skin, or insertion of an instrument or foreign material into the body." Section 2.1 of the procedure for Consents stated, "It is the responsibility of the treating physician ... to obtain informed consent." Section 2.5 indicated that written consent was to be documented on approved hospital forms. Review of the medical record for Patient A on 3/24/09 indicated that Patient A was admitted to the hospital on [redacted] for respiratory failure and pneumonia. Patient A had multiple anatomical and chronic conditions that compromised [redacted] ability to breath. Patient A was identified as having an allergy to iodine (chemical contained in the injected contrast material that was administered to Patient A for a radiographic imaging study on 3/23/08). In the 12 hours prior to the imaging study, steroid and antihistamine medications were administered to Patient A to reduce the risk of a serious allergic reaction to the iodine-containing contrast material. Within minutes of receiving the contrast injection, Patient A experienced breathing difficulty, low heart rate and low blood pressure requiring rescue	E1950	CORRECTIVE ACTION TAKEN: Unless the study is emergent, and delaying it could result in the loss of life or limb, the attending/ordering physician will obtain informed consent; In the ED, the ED physicians will get informed consent; For outpatient studies, the Radiologist will obtain informed consent. Medical Staff Policy on Consent revised, to exclude contrast studies, unless patient has a history of prior reaction/allergy, is pregnant, or has a high risk airway. Informed consent will be obtained for: *Patients with prior history of reaction to contrast media *Patients with allergy to iodine or contrast media *Pregnant patients *Patients with a high risk airway Rationale for not obtaining informed consent for all patients undergoing CT study with contrast: The ACR Practice Guidelines state, "Because of the documented low incidence of adverse events resulting from intravenous injection of contrast media, it may be exempted from the need for informed consent..." PERSON RESPONSIBLE: Jo-Lisa Miller, DI Manager Virginia Joyce, MD, VPMA DATES OF COMPLETION: Approved by the MEC on 11/18/09; Will go to the MPC on 12/3/09; Will go to the Board of Trustees on 12/14/09.	

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E1950	Continued From page 8 interventions and interrupted the imaging studies. Patient A did not respond to stabilizing treatments over the next two hours, and expired in the radiology suite. In collaborative record review of Patient A's medical record with the diagnostic imaging manager (DIM) on 3/24/09 at 9:30 a.m., the DIM could not locate any written informed consent for the contrast chest and neck CT (computerized tomography) studies ordered by the treating physician for Patient A on [redacted], despite iodine allergy being listed on the [redacted] admission orders, medication administration records, and Inpatient Admission Data Base form that was completed on [redacted] In an interview on 3/25/09 at 12:30 p.m. with Physician 10 who ordered the contrast CT studies for Patient A, Physician 10 indicated that she was aware of the increased risk for an allergic reaction to iodine-containing contrast. Physician 10 stated that she did discuss with Patient A and her daughter the indications for getting the CT studies, the risk for iodine reaction from the contrast material, the pre-procedure treatments intended to reduce the risk, and the lack of alternative studies to obtain necessary information about Patient A's breathing problems and neck pain. Physician A stated that she did not document that this discussion took place, but that both Patient A and her daughter consented verbally. In an interview with the diagnostic imaging manager (DIM) on 3/24/09 at 11:30 a.m., the DIM acknowledged that Patient A had a known Iodine allergy and was at risk for a serious reaction to the iodine-contalning contrast material. The hospital practice was to pre-medicate patients	E1950	MONITORING PROCESS: A random sample of 30 charts will be audited quarterly to ensure informed consent is being appropriately obtained for the patient groups listed above. Target: 90% compliance. Charts that fall out will be reviewed individually by managers. If it is a physician compliance issue, the case will be sent to the Chairman of the PI Committee for review. If it is a failure of the nursing or radiology staff, the appropriate manager will take action with the specific employee(s). This review will continue for 1 year and results will be presented quarterly to the medical staff committees.	

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E1950	Continued From page 9 with iodine reactions with Prednisone and Benadryl in the 24 hours prior to the procedure, which was done for Patient A. However, it was not hospital practice or policy to obtain written informed consent (provided by a physician) for this high-risk diagnostic treatment from patients with a history of iodine reactions. Instead, the imaging technicians were to review with the patient an information sheet that described some of the risks for reactions to injected contrast material, and then have the patient sign that they received the information. The injection policy did not require that the physician document that the physician had directly discussed the risks, benefits, and alternatives for contrast injection procedures with the patients. Review on 3/25/09 of Imaging Injection Policy 1032, revised 7/05 and in effect on [redacted], confirmed that contrast injections were to be supervised by emergency room physician or radiologist. It also indicated that "contrast screening forms are required with patient signature for examinations utilizing injection of contrast media." An updated Imaging Injection Policy 1032, revised 7/08 following the hospital's investigation of Patient A's death, now indicated that "contrast screening forms are required along with consent for IV contrast media injection" but did not indicate that a physician would obtain the patient's consent as required by the medical staff Consent Policy 4.3 (above). The Diagnostic Imaging Manager (DIM), in an interview on 8/20/09 at 3 p.m., indicated that written physician-obtained informed consents were not currently in practice for contrast procedures. In an interview with the Physician 15 on 8/20/09 at 3 p.m., Physician 15 confirmed that neither ordering physicians, nor radiologists, were	E1950		

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E1950	Continued From page 10 required to document that they had obtained informed consent for contrast procedures from the patients undergoing the procedures. He stated the radiology technicians talked to patients about the risk of the contrast. Physician 15 acknowledged that the severity of a contrast reaction (life-threatening) rather than the frequency, justified the need for informed consent. Physician 15 was aware that physicians cannot delegate the act of obtaining informed consent to non-physicians. The American College of Radiology Manual on Contrast Media pages 23-27, revised 9/09/08, was reviewed on 3/25/09. On pages 23-27 the adverse effects of iodinated contrast media were described. Life-threatening reactions were noted to appear identical to an anaphylactic reaction. Certain patients were at increased risk for adverse events, including patients with prior reaction to contrast injection and patients with thyrotoxicosis (elevated thyroid hormone levels). Severe reactions included very rapid cardiopulmonary collapse, bronchospasm (narrowing of large airway), laryngeal edema (swelling and narrowing of airway), seizure, hypotension (low blood pressure), and pulmonary edema (swelling and fluid accumulation in the lungs).	E1950		