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
	050025	A. BUILDING _____ B. WING _____	02/24/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNIVERSITY OF CALIFORNIA, SAN DIEGO MEDICAL CENTER	200 WEST ARBOR DRIVE, SAN DIEGO, CA 92103-8976 SAN DIEGO COUNTY

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	The following reflects the findings of the California Department of Public Health during an entity reported incident investigation. Entity Reported Incident Number: CA00175878 Category: State Monitoring Sub-category: Retention of a foreign object in a patient. Representing the Department: The inspection did not represent the findings of a full inspection of the facility. Title 22 Medical Service General Requirements 70203 (a) (2) A committee of the medical staff shall be assigned responsibility for : 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 record review, the facility failed to ensure that the manufacturer's recommendation for the insertion of a central venous catheter were followed, even though supervision was provided, for 1 of 1 (1) sampled patient. Therefore, Patient 1 required an additional invasive procedure to remove a retained guide wire (device made of flexible wire used to guide		RECEIVED APR 27 2009 CA LICENSING AND CERTIFICATION SAN DIEGO DISTRICT OFFICE SOUTH The involved Medical Staff have been re-educated regarding MCP 505.2E, Safe Medical Device Act Reporting, and the manufacturer guide-lines for the placement of the central venous catheter. Responsible Party: Department of Medicine, Residency Program Director A review of this policy has been discussed during the Internal Medicine Mortality & Morbidity conference, specifically stressing the	February 6, 2009 April 15, 2009

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Brenda Watson, RN	Regulatory Affairs - Asst. Director	April 27, 2009

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	Continued From page 1 placement of catheters) from his right atrium (chamber of the heart). Findings: Patient 1 was admitted to the hospital on 1/21/09 with diagnoses that included end stage liver disease and hepatic encephalopathy (disease of the brain) according to the admission face sheet. A review of Patient 1's medical record was conducted on 1/29/09 at 3:00 P.M. Patient 1 was transferred from another local hospital for a liver transplant evaluation. According to the physician's order sheet, Patient 1 was considered to be in critical condition at the time of his admission. The decision was made to insert a multi-lumen central venous catheter into Patient 1's right femoral vein (located in the groin area). According to the Invasive Procedure Note, dated 1/21/08, the central venous catheter procedure was performed at 11:00 P.M. The procedure was performed by a first year Intern with a third year Internal Medicine Resident in attendance for supervision. According to an addendum, written by the Intern, on the Invasive Procedure Note "the guide wire was left in the line." A physician's progress note, written on 1/22/09 at 4:00 A.M., stated "called by intern who placed R (right) femoral TLC (triple lumen catheter), concerned guide wire may have been retained in vessel during procedure." According to a chest x-ray report, taken on 1/22/09 at 5:00 A.M, "the tip of the guide wire traverses the IVC (inferior vena cava) and		Continued From page 1 inspection of the guidewire for integrity and that the entire guidewire is removed. Responsible Party: Department of Medicine, Residency Program Director In addition, the Invasive Procedure Note & Billing form has been revised to include documentation of removal of guidewire, inspection of guidewire, and verbal handoff to the RN. (Attachment A) Responsible Party: Department of Medicine, Residency Program Director; Risk Managment, Manager; and Regulatory Affairs A Patient Safety Alert (PSA) has been prepared for circulation highlighting guidewire removal. The key issues included in the PSA - Protect your Patient During Central Line Insertion: Think "W.A.R.D." - Ward,Assess, Remove & Document. The key issues to the PSA are as follows:	March 30, 2009 April 22, 2009

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Brenda Gutierrez, RN Asst. Director Regulatory Affairs | April 27, 2009

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	Continued From page 2 terminates in the right atrium (chamber of the heart). Interventional Radiology was then contacted to perform a second invasive procedure to remove the guide wire from patient 1's right atrium. A physician's progress note, written on 1/22/09 at 12:05 P.M., indicated that "IR (interventional radiology) was concerned about risks of procedure in coagulopathic patient" (defect in body's mechanism for clotting blood). Therefore, several blood products to promote clotting were administered to Patient 1 in preparation for the procedure to remove the guide wire. On 1/22/09 at 9:53 A.M. Patient 1 received 2 units of fresh frozen plasma (the fluid portion of two units of human blood). On 1/22/09 at 10:37 A.M., Patient 1 received Factor VIIA (one of the central proteins in coagulation). On 1/22/09 at 11:18 A.M., Patient 1 received eight additional units of fresh frozen plasma. And, on 1/22/09 at 11:18 A.M., Patient 1 received ten units of plasma cryoprecipitate (a precipitate rich in factor VIII needed to restore normal coagulation). On 1/22/09 at 5:00 P.M., Patient 1 underwent an "Intravascular (within the blood vessel) Foreign Body Retrieval" according to the Brief Operative Report. An interview was conducted, on 2/19/09 at 1:10 P.M., with the third year Resident who supervised the original catheter insertion procedure. The Resident stated that he watched the Intern perform all steps of the procedure. Some steps, he stated, he watched in more detail than others. The Resident thought that the Intern probably momentarily let go of the guide wire and the guide wire migrated into the catheter. Therefore, the		Continued From page 2 (Attachment B) Physician Placing Central Lines: (1) It is imperative, as you advance catheter over guidewire, that you ensure that the guidewire is secure & that you remove the guidewire after placement of the catheter. (2) After removing the guidewire, inspect the guidewire is intact. Document wire removal & inpsection on Form D1484 Invasive Procedure Note & Billing Supervising Physicians: You are responsible to actively oversee the procedure being performed. This includes, securing, removing and inspecting the guidewire, documentation of the procedure, and informing the primary nurse that the procedure is completed. Nurses: We strongly recommend that the primary nurse receive report from the physician who inserted the line that "WARD" guidelines were followed and	

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Brenda Mattson, RN | Asst. Director, Regulatory Affairs | April 27, 2009

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	Continued From page 3 guide wire would no longer be visible extending from the catheter. The Resident stated that he failed to notice this happening. An interview was conducted with the Director of the Internal Medicine Residency Program on 2/19/09 at 1:30 P.M. The Director indicated that it is the policy of the facility for interns and residents to complete five supervised femoral central venous catheter insertions prior to completion of their residency. The Director further stated that after performing five of these procedures the individual is "signed off" to perform the procedures unsupervised. The Director stated that the supervising resident had been "signed off" on insertion of a central venous catheter into the femoral artery. An interview was conducted, on 2/24/09 at 3:35 P.M., with the Intern who performed the catheter insertion procedure. This was the third central venous catheter this intern had performed since she began her internship in July 2008. The Intern stated that somehow she did not notice the guide wire had migrated into the catheter. The Intern further stated that a few hours after the procedure, at about 2:00 or 3:00 A.M. on 1/22/09, she realized that she had not removed the guide wire. The Intern stated that she called the Resident to inform him of the guide wire that may have been left in Patient 1's right femoral vein. An interview was conducted with the Director of Administrative Services on 2/24/09 at 3:45 P.M. The Director stated that the manufacturer's		Continued From page 3 documented. Responsible Party: Risk Management, Manager and Regulatory Affairs Monitoring of the Invasive Procedure & Billing form is accomplished through the UCSD Medical Center's on-going physician documentation audits/ tracer tool. Any issues identified are shared with Leadership; the Department Chair, Medicine; Nursing Leadership, and Nurse Manager. Actions will be taken as necessary. Responsible Party: Regulatory Affairs	May 1, 2009 x6 months

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Brenda Gallegos, RN | TITLE: Asst. Director, Regulatory Affairs | (X6) DATE: April 27, 2009

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	Continued From page 4 recommendations are expected to be followed when the clinical staff is using patient related supplies. The manufacturer's recommendations regarding central venous catheterization insertion was reviewed with the Intern on 2/24/09 at 3:50 P.M. The manufacturer's recommendations indicated that the individual performing the procedure should "thread tip of multiple lumen catheter over spring-wire guide. Sufficient guide wire length must remain exposed at hub end of catheter to maintain a firm grip on the guide wire...Precaution: Catheter clamp and fastener must not be attached to catheter until spring-wire guide is removed." The Intern acknowledged that by not removing the guide wire she failed to follow the manufacturer's recommendation for insertion of the central venous catheter. An exit conference was conducted with the Director of Administrative Services on 2/24/09 at 4:00 P.M. at which time the Director was notified that an adverse penalty may be issued for the facility's failure to follow the manufacturer's recommendations for insertion of a central venous catheter even though supervision was provided. This necessitated a second invasive procedure to remove the retained guide wire from Patient 1's right atrium.			

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Brenda Gattyon, RN | Asst Director, Regulatory Affairs | April 27, 2009

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