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
	050324	A. BUILDING _____ B. WING _____	04/26/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SCRIPPS MEMORIAL HOSPITAL - LA JOLLA	9888 GENESEE AVENUE, LA JOLLA, CA 92037 SAN DIEGO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit:
	
	Complaint Intake Number:
	CA00189315 - Substantiated
	
	Representing the Department of Public Health:
	Surveyor ID # 16509, HFE II Supervisor
	
	The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility.
	
	Health and Safety Code Section 1280.1(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.
	
	AMENDED 2567
	The California Department of Public Health has withdrawn the 2567 for the Administrative Penalty # 080006734 issued to the facility on November 30, 2009. The Department is re-issuing the 2567 as written below.
	
	The following reflects the findings of the California Department of Public Health during an Entity reported incident investigation conducted from 5/27/09 through 6/26/09. Entity Reported Incident: # CA00189315
	
	Category: Retention of a foreign object in a patient
			a. How the correction will be accomplished, both temporarily and permanently.
			
			• The correct process for deployment and removal of angio guide wire in-services were held for all CVL staff that included:
			  • Review of catheters and devices used during the procedures
			  • Deployment technique with a focus on guide wire placement and removal
			  • Deployment steps including statement of: " Wire Out " to be called by the technologist for staff and supervising physician notification
			  • Documentation of "Wire Out" in the cath lab documentation module and signature by the technologist
				July 2009

Event ID:KW5R11 4/26/2011 8:28:31AM

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[signature]	CHIEF EXECUTIVE	5/6/11

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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	Continued From page 1 The investigation was limited to the specific allegation(s) reported and does not represent the findings of a full inspection of the facility. Representing the California Department of Public Health: # 17130 Health and Safety Code 1280.1(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. Title 22 70435 Cardiovascular Surgery Service Staff. (a)Cardiovascular catheterization laboratory. (3) Two persons (registered nurses or cardiovascular technicians) shall assist during the performance of all cardiac catheterization procedures. These personnel shall be trained in the use of all instruments and equipment and shall be supervised by a physician Based on interviews and record reviews, Facility 1 failed to ensure adequate supervision of a cardiovascular technician [CVT 1] while he deployed a femoral artery closure device at the end of a cardiac catheterization procedure performed on Patient A. As a result, a twenty-eight (28) inch guide wire was retained in the patient's right common femoral artery and found 29 days later during a second cardiac catheter procedure. Findings:		• The above in-services were followed by a return demonstration of all staff. • Interventional cardiologist and CVL staff will continue to remain in the CVL room until the patient is deemed stable for transfer to Recovery Room or patient care unit. **b. The title or position of the person responsible for correction.** Manager of CVL Medical Director of CVL **c. Description of the monitoring process to present recurrence of the deficiency.** Medical record audits on patients who receive closure devices to validate that the technologist who deploys the closure device is signing the record were performed for 90 days with satisfactory compliance. Results were shared and discussed at the staff meeting Any issues identified during femoral closure device deployment will be addressed by the CVL staff and interventional cardiologists. The Manager, CVL and Medical Director, CVL will be notified.	Nov. 2009 Nov. 2009

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	Continued From page 2 Patient A, an 82 year old male, was admitted to Facility 1 on 4/20/09 with diagnoses which included chronic total blockage of a coronary artery, unstable angina, and post coronary artery bypass surgery. On 4/21/09, Patient A underwent a cardiac catheterization and was discharged home on the same day. Twenty nine days later on 5/19/09, Patient A was admitted to Facility 2 for a second heart catheterization. At the time of the second heart catheterization on 5/19/09, a 28 inch long (70 cm) guide wire from the initial heart catheterization done at Facility 1 was found in Patient A's right (common) femoral artery. The guide wire extended from the descending aorta up to the aortic arch. The wire was removed and Patient A was discharged home on 5/20/09. On 5/27/09, the medical record at Facility 1 was reviewed. The Preoperative History and Physical dated 4/20/09 showed that Patient A had "unstable angina." The cardiologist planned to proceed with a cardiac catheterization. On 4/21/09, the procedure was performed. On the same day, the cardiologist documented that an Angio-Seal device was used to close the femoral artery at the end of the procedure. [Angio-Seal is a vascular closure device used to seal the puncture site (the femoral artery) in patients who have undergone diagnostic heart catheterizations. The procedure included insertion of a guide wire into the femoral artery. At the completion of the procedure, the guide wire is removed.		**d. Date the immediate correction of the deficiency will be accomplished. Normally this will be no more than thirty (30) days from the date of the exit conference. However, in the case of civil money penalties (citations) being used, the correction of the deficiency may be required to begin immediately with all correction of the deficiency being completed in less than thirty (30) days.**	July 2009

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The Post Catheterization Progress Notes dated 4/21/09 indicated that the Angio-Seal device was deployed by CVT 1.

During an interview on 5/29/09 at 11:05 A.M., CVT 2 stated that at the end of the procedure, the physician left the procedure table and CVT 1 closed the site. Per CVT 2, the physician did not remain at the procedure table to supervise closure while CVT 1 deployed the Angio-Seal device.
During in interview on 5/28/09 at 3:00 P.M., CVT 1 did not recall deploying the Angio-Seal device on Patient A.

On 5/29/09, Patient A's medical record at Facility 2 was reviewed. On 5/14/09, Patient A was referred to a cardiologist at Facility 2 for a repeat heart catheterization. On 5/14/09, the cardiologist's Nurse Practitioner examined Patient A. The Nurse Practitioner documented in the consultation that Patient A complained of pain in the right groin and had a "lump" at the site of the initial heart catheterization at Facility 1. On 5/19/09, the repeat heart catheterization was done at Facility 2. The Cardiac Catheterization Laboratory electronic record dated 5/19/09 showed that a guide wire from the prior heart catheterization at Facility 1 was retained in the right common femoral artery. The wire was subsequently removed.

During a telephone interview on 6/26/09 at 11:50 A.M., the cardiologist at Facility 2 who found the retained guide wire stated that the

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guide wire probably caused "sensitivity" in the groin.
Facility 1 failed to ensure supervision of CVT 1 while he deployed a closure device on Patient A's right common femoral artery. The lack of adequate supervision resulted in the retention of a 28 inch long guide wire in Patient A's femoral artery for a period of 29 days. This caused Patient A pain and placed him at risk for complications such as infection, sepsis, blood clot formation, and migration or perforation of a blood vessel from the retained guide wire.

The facility's failure to properly supervise the CVT in the proper deployment of a closure device on Patient A is a deficiency that has caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health & 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).

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