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
	050090	A. BUILDING _____ B. WING _____	01/23/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Sonoma Valley Hospital	347 Andrieux St, Sonoma, CA 95476-6811 SONOMA COUNTY

(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
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00296060 - Substantiated Representing the Department of Public Health: Surveyor ID # 20307, Medical Consultant 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 1280.3: 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. Penalty number: 110011032 A 010 1280.1(a) Health & Safety Code 1280 (a) Subject to subdivision (d), prior to the effective date of regulations adopted to implement Section 1280.3, if a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation.		**AMENDED**	

Event ID:8MMR11 6/16/2015 3:10:49PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Leslie Lovejoy TITLE Chief Quality Officer (X6) DATE 6/29/15

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s): 1 thru 5

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.

6/29/15 11:30 AM POC accepted. Leslie Lovejoy notified JG

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	Findings: (See A0347) A 012 1280.1(c) Health & 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. Findings: (See A0347) E 347 T22 DIV5 CH1 ART3-70223(b) (2) Surgical Service General Requirements (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of 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 document review, the hospital failed to follow its instrument count policy and failed to prevent retention of a foreign object in Patient 1, when a retained patella protector was left in after surgery, resulting in pain and the need for a		1. The Medical Executive Committee at Sonoma Valley Hospital is responsible for the development, maintenance and implementation of written policies and procedures. At the time of the event the President of the Medical Staff, with input from the Medical Executive Committee, reviewed the event and a team was formed to complete an intense analysis of the event. The team consisted of frontline operating room staff, the Chief Medical Officer, Chief Nursing Officer, Chairman of the Surgery Department, Director of Perioperative Services, Chief Quality Officer and the Risk Manager. The intense analysis identified root causes that contributed to the event and an action plan was developed on 1/24/2012. Responsible Person: Chief Medical Officer Action Plan A. All patients undergoing an elective Total Knee Replacement are at risk for the deficient practice. The following system changes have been completed to ensure that this does not recur.	1/24/2012

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	second operative procedure to remove it. The facility's failure to implement written policies and procedures requiring accurate counting of instrumentation during a surgical procedure resulted in pain and a second operation was a violation of Section 70223(b) (2) of Title 22 of the California Code of Regulations and was a deficiency that caused, or was likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code 1280.1. Findings: In interview on 01/31/12 at 11:15 a.m., Staff A stated that on 01/12/12, Physician B discovered that Patient 1 had a retained patella protector in his thigh following knee surgery on 01/4/12. A patella protector is a round metal disc, two inches in diameter and one quarter inch thick, with three one quarter inch posts. It is used in total knee replacement procedures to protect the under surface of the patella [knee cap] while the knee joint is being prepared to receive the artificial knee joint. The patella protector is removed when the joint has been replaced by the permanent hardware. Staff A stated that the patella protector was retained because no staff member was keeping track of it. Staff A stated that the representative of the orthopedic appliance company who took inventory of the instruments after the operation told Staff C and Staff D that the patella protector was unaccounted for. Staff C and Staff D		Continued From Page 2 1. The Policy and Procedure entitled: Counts: Sponges, Sharps and Instruments was revised on 2/15/2012 to include the following language: "Instruments will be counted on all procedures where there is a reasonable danger that an instrument could be accidentally retained by the patient. This includes identifying in the preliminary, first and final counts any and all high risk instruments included in consignment/vendor trays". Responsible Person: Director, Perioperative Services 2. The electronic documentation was reviewed and the plan of care section which includes sponge, sharps and instrument counts was amended to include a mandatory field requiring documentation of high risk instrument documentation, including patella protectors, patella sizers and fixation pins for elective Total Knee Replacement surgeries. Responsible Person: Director, Perioperative Services 3. The Count: Sponges. Sharps, and Instrument Policy was revised and directs the OR nursing staff to record the revised count information above in the amended plan of care located in the electronic intra-operative record. Responsible Person: Director, Perioperative Services	2/15/2012 3/7/2012 2/15/2015

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	did not notify Staff E, the surgery manager that the piece was missing until 01/9/12. Staff A stated that Staff C and Staff D believed that lost pieces can fall into folds of the surgical drape and get discarded. They did not consider the possibility that the piece could have been left in the patient. Staff A stated that the orthopedic appliance representative notified Physician B on 01/9/12 that the piece was missing, stating that it would be hard to do the next case without it. Staff A stated that Patient 1 called Physician B on 01/10/12 complaining of pain. On x-ray, the patella protector was clearly visible in Patient 1's leg. It was removed surgically on 01/12/12. In interview on 01/31/12 at 11:40 a.m., Staff E stated that the patella protector was not one of the items included in the operating room's surgical instrument count protocol, and its absence was not noticed until after the patient left the operating room. In interview on 01/31/12 at 12 noon, Physician B stated that the patella protector's role is to protect the patella from fracture during the joint replacement procedure. He stated that disturbances occur during surgery, and he did not account for its absence. He stated that the protector comes out and should go back on the table when he is ready to place the permanent plate. He stated that the device was removed. He stated that he remembered taking it out. He stated that he did not know how it got in the leg. Record review on 01/31/12 demonstrated that the		Continued From Page 3 4. Operating Room Staff were provided education, during staff meetings and on a one to one with the department director, on the changes to the policy and the documentation in the electronic record as it pertains to the count of instruments for all procedures where the body cavity is entered where there is reasonable danger that an instrument could be accidently retained by the patient, such as patella protectors, patella sizers and fixation pins. Responsible Person: Director, Perioperative Services Monitoring: 1. 100% of operating room scrub techs and circulating nurses have been educated to the policy and documented changes and all new employees will be oriented to the new policy and documentation requirements as part of the department's orientation. Responsible Person: Director, Perioperative Services	2/29/2012 2/29/2012

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	01/4/12 operating room report for Patient 1 included a section titled "risk for injury related to retained foreign object." A list of the items to be counted consisted of suture needles, sponges, injection needles, blades, and cautery. Preliminary, first, and final counts were correct. Review of Physician B's operative report demonstrated that it was absent mention of removal of the patella protector. On 01/31/12, observation of Patient 1's x-ray, taken on 01/10/12, demonstrated a disc-shaped object clearly visible beside the knee joint. Review of hospital policy "Counts - Sponges, Sharps and Instruments" revised 12/07, indicated the requirement that instruments will be counted on all procedures where a body cavity is entered and will be counted on all procedures "where there is a reasonable danger that an instrument could be accidentally retained by the patient." 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).			