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
	050272	A. BUILDING _____ B. WING _____	03/02/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Redlands Community Hospital	350 Terracina Blvd, Redlands, CA 92373-4850 SAN BERNARDINO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00388156 - Substantiated Representing the Department of Public Health: Surveyor ID # 26774, HFEN 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. Health and Safety Code Section 1279.1 (c): "The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made." The CDPH verified that the facility informed the patient or the party responsible for the patient of the adverse event by the time the report was made." REGULATION VIOLATION: Health and Safety Code sections 1271.1, 1280.1 and Title 22, California Code of Regulations, section 70433 Cardiovascular Surgery Service General Requirements		Facility ID # 240000046 Complaint Intake Number: CA00388156 – Substantiated Note: There are no ID Prefix Tags identified on the 2567 Redlands Community Hospital ("Hospital") was notified by the involved physician ("MD 2") that a retained foreign object had been observed in Patient A. A. Immediately upon receiving notice from MD 2, the Hospital's Quality and Patient Safety Manager notified the Hospital's leadership team, including the CEO, Chief of Staff, and vice-president and director level personnel from the areas at issue. Reflecting its collaborative focus and commitment to involving all stakeholders in ensuring patient safety and quality of care, additional notification was made to the following: -Quality & Patient Safety Council by the Patient Safety Manager. -Medical Executive Committee by the Vice President of Patient Care Services. -Hospital's Board of Directors Patient Care Committee by the Vice President of Professional and General Services.	2/12/14 2/12/14 2/13/14 2/13/14 2/20/14

Event ID:L42I11 3/12/2015 1:49:37PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE J Larry D. J Larsen TITLE VP (X6) DATE 3/24/2015

By signing this document, I am acknowledging receipt of the entire citation packet, Page(s). 1 thru 10

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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	1271.1 (b)(1)(D): (b) For purposes of this section, "adverse event" includes any of the following: (1) Surgical events, including the following: (D) Retention of a foreign object in a patient after surgery or other procedure, Excluding objects intentionally implanted as part of a planned intervention and objects prior to surgery that are intentionally retained. AND 1280.1 (a) (c)(d) (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. (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. (d) This section shall apply only to incidents occurring on or after January 1, 2007. With respect to incidents occurring on or after January 1, 2009, the amount of the administrative penalties		The Quality and Patient Safety Manager promptly initiated an internal investigation of the matter, which was undertaken by a multidisciplinary team comprised of: the Director of Quality & Medical Staff Services; Quality & Patient Safety Manager; VP Patient Care Services, VP Professional and General Services, Director of Imaging Services; Director of Surgical Services; Director of Risk; the Special Procedures Area RN, Scrub Tech and Procedure Tech; and MD1 and MD2, the two cardiologists who participated in the survey process (the "Multidisciplinary Team"). The Hospital's VP of Patient Care Services reported the event to the California Department of Public Health ("CDPH") via facsimile correspondence. The Director of Imaging Services and the Nurse Manager of the Cardiac Catheterization Lab ("CCL") informed Patient A that the occurrence was reported to the CDPH, consistent with State of California requirements. The provision of this notice was documented in Patient A's medical record.	2/12/14 2/14/14 2/19/14

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	assessed under subdivision (a) shall be up to one hundred thousand dollars ($100,000) per violation. With respect to incidents occurring on or after January 1, 2009, the amount of the administrative penalties assessed under subdivision (a) shall be up to fifty thousand dollars ($50,000) for the first administrative penalty, up to seventy-five thousand dollars ($75,000) for the second subsequent administrative penalty, and up to one hundred thousand dollars ($100,000) for the third and every subsequent violation. AND 70433 (a)(4): (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 and medical staff where such is appropriate. These policies and procedures shall include provision for at least: (4) Recommendations regarding equipment used, procedures performed and staffing patterns in the catheterization laboratory and cardiovascular surgery units. Based on interview, and record review, the facility failed to ensure that a surgical sponge was extracted from Patient A's chest after the Automatic Implantable Cardiovert-Defibrillator (AICD) generator (delivers shocks to the heart if heart rhythm becomes irregular), was removed and		Immediate Corrective Actions The Director of Surgical Services and the Director of Imaging Services reviewed the content of the Hospital's existing Surgical Services Policy C-18 "Counts of Surgical Items" ("Policy C-18"), including the process and equipment to use during open procedures (i.e., the Count-EZ Sponge Counter Bag System), and determined that its content was appropriate to enhance the standardization in the cardiac catheterization lab ("CCL"). The Director of Surgical Services and the Director of Imaging Services prepared a new Special Procedures Policy, 5.06, "Counts of Sponges, Sharps, and Other Applicable Items" ("Policy 5.06") the content of which mirrored the relevant content of Policy C-18 with minor changes to address particular supply and personnel needs in the CCL. The Director of Surgical Services, the Director of Imaging Services and the Imaging Services Manager provided an in-service to all hospital employees who work in the CCL to review the new Policy 5.06, the Association of Operating Room Nurses guidelines entitled "Perioperative Standards and Recommended Practices" (2013 Ed., p. 305-319) ("AORN Guidelines"), and Joint Commission Sentinel Event Alert entitled "Preventing Unintended Retained Foreign Objects" (Issue 51, Oct. 17, 2013) ("SE Alert").	2/12/14 2/13/14 2/13/14

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	replaced on August 14, 2013. This failure resulted in Patient A's infection at the site which progressively worsened, until the surgical sponge was visible through an open area in the chest wall on February 10, 2014. Patient A also required antibiotics and a second surgical procedure to remove the AICD. FINDINGS: A review of the physician's (MD 1) history and physical dated August 14, 2013, indicated Patient A had a history of: diabetes mellitus (body cannot produce or utilize insulin) complicated by neuropathy (circulatory impairment). The patient had previously undergone both three vessel and four vessel coronary bypass grafts (replacement of plugged arteries in the heart) and suffered left ventricular dysfunction (ventricle does not have enough strength to pump the blood through the body), which required an AICD implant. A review of the operative report dated August 14, 2013 indicated the cardiologist (MD 1) documented the following: "had placed an antibiotic impregnated swab into the prior generator pocket...The antibiotic-impregnated swab was removed. The pocket was lavaged (washed out); the generator was connected to its leads...Generator placed into the pocket..." Under a section of the operative report entitled, "Impression," MD 1 documented the following: "Successful Medtronic, model D314DRG, dual mode, dual chamber, dual sensing, pacemaker implantation. Leads appear to be in excellent condition. No obvious complications occurred."		The Chief of Staff sent a memorandum outlining required training for physicians who perform procedures in the CCL, which training included a review of Policy 5.06, the process and equipment identified in the policy (i.e., the Count-EZ Sponge Counter Bag System) for use during open procedures, AORN Guidelines, and the SE Alert. All physicians who performed open procedures in the CCL were required to and did complete training prior to performing any additional CCL cases. The Director of Surgical Services provided this training. The Surgical Specialties Chairman approved the merger of Policy 5.06 and Policy C-18 into a hospital-wide Patient Care Policy C-127, entitled "Counts of Surgical/Procedural Items" ("Policy C-127"). This merger was undertaken by the Hospital in order to ensure consistency in practice across all locations performing open procedures. Policy C-127 includes content consistent with the former Policy 5.06 and former Policy C-18.	2/14/14 Beginning on 2/13/14 2/26/14

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	A review of the "Chronological Log," recorded by the nursing staff at the time of the procedure on August 14, 2013, indicated Patient A arrived in the procedure room at 11:45 AM. At 12:06 PM, the antibiotic-impregnated sponge was documented as placed in the pocket portion (where the AICD had been removed). At 12:11 PM, the antibiotic-soaked sponge was removed, and the pocket was flushed by antibiotics. Under the Chronological Log section entitled, "End Studies," the following information was listed: Sponge count (pre-count and post count) "40 pre-cath and 40 post-cath." Patient A was discharged to home on August 14, 2013 at 12:35 PM, with a prescription for Keflex 500 mg (an antibiotic), and written instructions for a follow up appointment with MD 1. A review was conducted of the MD 2's notes summarizing a visit with Patient A dated February 10, 2014 (six months after the defibrillator was placed). The summary indicated that Patient A called to say there was leaking from the defibrillator pocket. MD 2 documented Patient A's skin had eroded through an area about 2 cm by 2 cm (1 cm is equal to 2.54 inches) size, and a sponge had protruded through the eroded area of skin. MD 2 further described his attempt to remove the sponge, however he was only able to remove a portion and was unsuccessful in extraction of the entire sponge. MD 2 further noted the decision to leave the retained sponge in the patient along with the defibrillator until explantation (removal) of both could occur later that week. MD 2 further indicated, "The		B. Ongoing Corrective Actions The Director of Imaging Services ensures that hospital employees and all physicians who participate in open procedures in the CCL are educated on an ongoing basis regarding counts of items prior to working in the CCL, through a program of in-person didactic sessions and direct observation (1) for physicians, at the time of granting of privileges for procedures performed in the CCL and as part of CCL orientation, and (2) for staff, at the time of hire, upon completion of the 90-day post-hire skills checklist and through annual staff training sessions thereafter. The education curriculum includes Policy C-127, AORN Guidelines, and SE Alert. Post-tests are conducted to ensure comprehension, and remedial training is provided to any individual who fails to successfully complete the post-test. C. Monitoring of Compliance To ensure consistent adherence to Policy C-127, a program of direct observation of 100% of sponge counts for open pocket procedures was performed. These observations were performed by the Director of Surgical Services (or designee) and compliance was reported to the Director of Imaging Services. Audits were conducted monthly and continued until 100% compliance for three (3) consecutive months was achieved.	Beginning 2/13/14 2/18/14 Beginning 3/1/14

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	patient wasn't started on antibiotics since there was no evidence of any infection at this time." A review of MD 1's notes summarizing a visit with Patient A on February 13, 2014. MD1 set forth the following: "I first saw Patient A at the request of [Patient A's physician] on August 14, 2013. He had an ICD (Medtronic) which was requiring replacement due to end of life parameters." MD1 described further that Patient A did well with the procedure to remove the ICD but that later in the year Patient A started having erythematous (reddened area) changes in the lower portion of the pocket (area on chest where implant was inserted). MD1 further described how Patient A was seen at his office by another doctor while MD1 was on vacation on January 28, 2014. At that time there was some erythema and the patient was started on Bactrim twice a day for seven days (antibiotic). MD 1 described further that Patient A's symptoms did not improve. MD1 described how he eventually spoke to Patient A on February 12, 2014 and explained, "that the retained sponge was the cause of the ICD pocket problem. I took responsibility for this error." MD 1 further documented he told Patient A to come in for the procedure to explant the AICD generator and remove the retained surgical sponge. During an interview on February 27, 2014 at 2:40 PM with the Director of Quality and Patient Safety, she stated that Patient A had the generator explanted on February 25, 2014, and was given a Life Vest to wear.		Audits were then conducted quarterly until 100% compliance for three (3) consecutive quarters was achieved. Audit results are reported by the Director of Imaging Services or designee to the Medical Staff's Quality and Patient Safety Council ("QPSC"). Per the QAPI Process, the QPSC reports results to the Medical Executive Committee, which in turn reports results to the Patient Care Committee of the Hospital's Board of Directors, which in turn reports to the Hospital Board of Directors. The VP of Patient Care Services and the VP of Professional & General Services share the overall responsibility for these corrective actions and monitoring of continued compliance.	10/9/14 4/10/14

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	A review of the patient care notes dated 2/26/14 at 5:39 PM reflected that the Life Vest was placed on Patient A and activated. Patient A was instructed to keep it on 24 hours per day and 7 days per week. Review of Patient A's discharge instructions dated February 26, 2014, showed that Patient A was discharged home with the Live Vest in place and with orders for daily intravenous (through the vein) antibiotics and weekly lab tests. Review of the physician's procedure report dated 8/19/14, reflected that Patient A received a new generator that was implanted on 8/19/14, approximately 5 1/2 months after the prior generator was removed and Patient A had been fitted with a Life Vest to wear. During a phone interview with MD 1 on February 28, 2014, at 11:15 AM, MD 1 explained, "I may have put two sponges in inadvertently and forgot I had put two in. I just remember thinking Patient A had a high risk for infection at the time." When asked why sponge counts in the cardiac catheterization lab were not done as is the process in the operating room, he replied that the scrub tech was meticulous in being sure to say, "sponge in," and "sponge out." MD 1 stated he later tried to recreate the scenario by intentionally placing a second sponge in another patient and then feeling the area with his gloved finger. He stated, "I could not feel the sponge, it felt like tissue, and then I removed them both MD 1 stated during the interview on			

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	February 28, 2014 that "the facility was now doing visual of the sponges and a count before and after." MD 1 also stated that since this incident, the facility is also "doing fluoroscopy to ensure no sponge can be left in because the sponges are radio-opaque, and show up on X-ray." MD 1 further advised that at the time Patient A's generator was changed on August 14, 2013, X-rays only were completed on new implants. MD 1 advised that since this incident he will now slightly retract the wound edges and look inside the pocket I have created." MD 1 further advised, "It was a systems error, but I was responsible. It was unfortunate, but resulted in a systems change and we were able to fix the problem." During an interview with the Director of Quality and Patient Safety (DQPS) on February 27, 2014 at 3:55 PM, The DPQS confirmed there was no procedure for pre-operative or post-operative counting of sponges in the cardiac catheterization lab on August 13, 2014, the date of Patient A's procedure. On February 27, 2013 at 4:35 PM, an interview was conducted with a Catheter Lab Assistant (Scrub Tech 1). When asked to describe the process for accounting for surgical sponges, she stated, "Prior to the sponge being left in Patient A, we had not counted sponges. One would get soaked in antibiotic solution, one goes in, and one comes out. On initial pacemaker and generator implants, we would do X-rays, but this was not a new one." During further interview, when asked to describe the			

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	process of performing implants and explants, Scrub Tech 1 stated, "They (the physicians) make a pocket but small, kind of like a pita pocket. The antibiotic sponge goes in first, then the leads are placed. The sponge would then be removed, the pocket flushed with an antibiotic solution. The device would then be hooked up, and then placed inside of the pocket. This was when the X-ray would be taken to ensure no lead wires came loose, then the pocket would be sewn up." During an interview conducted with the circulating Registered Nurse 1 (RN 1) on February 27, 2014 at 4:45PM, she indicated that she had functioned as the circulating nurse during the procedure on August 14, 2013 for Patient A. When asked if they counted sponges pre and post operatively she replied, "At the end of the procedure, the scrub tech would call out the count and we would document it on the record." An interview was conducted with Registered Nurse 2 (RN 2) on February 28, 2014 at 9:30 AM. When asked how many sponges the procedure started with for Patient A, she replied, "We start with 40 and end with 40, and the scrub tech just says the amount [of sponges] and we write it down." When asked if there were any unusual distractions during this procedure for Patient A she stated, "No, it went smoothly." When asked for a copy of the facility's policy and procedure for counting surgical sponges in the cardiac catheterization lab, RN 2 stated they did not have a policy at the time Patient A had the defibrillator replaced.			

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	The facility's failure to create and implement policies and procedures for the counting of surgical sponges before, during and after a procedure in the cardiac catheterization lab, resulted in retention of a surgical sponge in Patient A's chest wall, infection and skin breakdown. Patient also had to undergo physician's attempts to remove the sponge, and further required both a surgical explantation procedure to remove both the sponge and AICD, as well as a further surgical re-implantion of Patient A's AICD. In addition, Patient A had to wear a Life Vest while waiting for the prior pocket to heal before re-implantation. The facility's failure to account for surgical sponges during a procedure 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 1280.3. 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).			