[redacted] 3/11/09

PRINTED: 02/25/2009
FORM APPROVED

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA930000100	A. BUILDING _____ B. WING _____	12/29/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SAINT JOHN'S HEALTH CENTER	1328 22ND ST SANTA MONICA, CA 90404

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000	Initial Comments The following reflects the findings of the Department of Public Health during a Complaint visit: Complaint Intake Number: CA00172164 - Substantiated The inspection was limited to the specific facility adverse event investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: [redacted] RN-HFEN [redacted] RN-HFEN 1280.1(c) Health & Safety Code Section 1280 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 likely to cause, serious injury or death to the patient.	E 000	(See cover letter for description of Exhibits)	
47	Deficiency Constituting Immediate Jeopardy T22 DIVS 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	E-347	At the time of this incident, the Hospital had a Policy and Procedure in place to address the Provision of Care, Treatment and Services in the Department of Surgery. **Plan of Correction:** Following receipt of the Statement of Deficiencies the Hospital has taken the following steps: Effective December 11, 2008, a Policy and Procedure titled "Fire Prevention in the Operating Room" was adopted. (A copy is marked as Exhibit "A".) This Policy and Procedure was adopted effective December 11, 2008, with specific reference to the Joint Commission	

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HEALTH FACILITIES
DIVISION

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(X6) DATE
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If continuation sheet 1 of 8

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E 347	Continued From Page 1 This RULE: is not met as evidenced by: Based on review of Patient A's clinical records, a review of the facility's policy, and interviews with staff, the facility failed to ensure Surgical Services Electrocautery Procedures were implemented by failing to ensure the Electrocautery Unit (ESU) was operated at the lowest possible power setting and the power settings were confirmed verbally between the user and the operator during a surgical procedure in the Operating Room (O.R.). This deficient practice resulted in Patient A sustaining 2nd and 3rd degrees burns to the face and left eye while the patient was undergoing eye surgery. Patient A was transferred to the intensive care unit for further management, and was subsequently discharged to general acute care hospital #2 where she underwent procedures for debridement of her left eye and debridement and autografting to the face. Finding: On December 18, 2008, an unannounced visit was made to investigate a facility reported incident regarding Patient A sustaining burns during a surgical procedure in the O.R. On December 18, 2008, a review of the medical record disclosed Patient A was admitted to the facility on December 9, 2006 for a bilateral eyelid blepharoplasty (A functional or cosmetic surgical procedure intended to reshape the upper or lower eyelid by the removal and/or repositioning of excess tissue as well as by reinforcement of surrounding muscles and tendons). The intraoperative nurses notes dated December 9, 2008, revealed that Patient A was transferred to the O.R. at 9:06 a.m., on December 9, 2008, According to the anesthesia operative notes	E 347	on Accreditation of Health Care Organizations, November, 2006 National Patient Safety Goals, the Association of Peri-Operative Registered Nurses, AORN 2008 Standards, Recommended Practices and Guidelines, and AORN Fire Safety Tool Kit, *Be Prepared To Prevent and Respond*. This Policy and Procedure addresses specifically "head and neck procedures" to assure a minimal build up or accumulation of N_2O and O_2 beneath drapes. (See p.1,(ii)(a).) To address any potential danger arising from utilization of supplemental oxygen in the presence of an ESU/Laser the policy stipulates that oxygen should be stopped at least one minute before use of the ESU/Laser and the anesthesiologist with the cooperation of the surgeon, is responsible to effect compliance with the requirement and stipulates that "Surgical Team communication is essential." Further the Surgical Team is and, specifically, the anesthesiologist is to question the need for O_2 for open delivery on the face and suggests that room air or $FIO_2 \leq 30\%$ for open delivery be utilized in the presence of ESU. (See page 1(ii)(c).) The Policy and Procedure further specifies emergency procedures to be undertaken in the event of fire of discovery of smoke. (See page 2 - page 4.) Specifically, with respect to Electro Cautery use a Policy and Procedure had been in effect which was last reviewed and adopted effective May 30, 2003. A specific reference to the "Association of Peri-Operative Registered Nurses, AORN 2008 Standards, Recommended Practices and Guidelines." It has since been	

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E 347	Continued From Page 2	E 347	reviewed and revised effective January 16, 2009. A copy of said Policy and Procedure is marked Exhibit "B."	

dated December 9, 2008 at 10:22 a.m., "a spontaneous fire broke out onto Patient A's face from the bovie tip and the oxygen mask." The notes also indicated that the drapes and oxygen mask were immediately removed from the patient's face, the oxygen was shut off, and the fire wounds on Patient A's face were covered with wet towels.

In a telephone Interview with Employee 1 on December 29, 2008 at 1 p.m., she stated Patient A was prepped and draped for a routine facial surgery. She stated the bovie cautery device (ESU) was located at the foot of the surgical bed, and the power settings of the cautery device were on 3 watts, for the cutting of the skin arid 3 watts for the coagulation (to prevent bleeding).

An Interview was conducted with M.D. 1, on December 18, 2008 at 10:30 a.m. M.D. 1 stated, "I believed the fire could had been caused by the pooling of oxygen in an oxygen-enriched environment, and possibly the increase settings of the bovie cauterizer, which was, according to the intraoperative notes, was increased to 10 watts and 8 watts." The Intraoperative Case Record dated December 9, 2008, documented the bovie cautery machine, ESU, was set at 10 watts for the cutting of the skin and 8 watts for the coagulation.

During a further Interview with Employee 1 on December 29, 2008 at 1 p.m., she stated that she was not aware that the power settings of the bovie cauterizer were at 10 watts at the time because she had stepped out of the O.R. However, she stated she later found out that Employee 3 had increased the power settings of the bovie cautery machine to 10 watts and 8 watts with a "Qtip" when she stepped out of the O.R. She also stated that she observed M.D. 2

As noted in the Statement of Deficiencies this Policy and Procedure previously required that the Electro Cautery unit was to be (a) operated at the lowest possible power setting and (b) the power setting should be confirmed verbally between the user and the operator.

The Policy and Procedure has now been revised effective January 16, 2009, and specifically addresses various areas of potential hazards stipulating that the "Proper care and handling of electro surgical equipment is essential to patient and personnel safety and should be used in a manner that minimizes potential for injury."

The Policy and Procedure focuses on specific areas of potential hazards in Electro Cautery use, including PROCEDURE (specifically addressing "Operation of Unit," "Patient Return Electrode," and "Active Electrode.") It requires in "Operation of Unit" that power settings be confirmed before activation, the ESU is to be utilized at the lowest possible power setting, and that "power setting should be confirmed verbally between the user and operator." The "Patient Return Electrode" stipulates that the circulating nurse is to apply and remove dispersive electrodes and assess and document the patient's skin condition both before and after ESU use. Further, it requires that all electrodes should be of an appropriate size for the patient and "NEVER" [b] altered (cut)." Recognizing that an electrode may cause a patient burn, specific areas are delineated and it is required that such an electrode may not be placed over those areas

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E 347	Continued From Page 3 working on the patient's left eyelid, when she observed the fire under the drapes. A further interview with M.D. 1 on December 18, 2008 at 10:30 a.m., as well as a review of the anesthesia notes, dated December 9, 2008, revealed that Patient A was receiving 4 liters of oxygen through an open oxygen system (mask). M.D. 1 also stated that the surgeon had not informed him that the power settings of the bovie cautery machine were increased. He stated that the oxygen should have been shut off and/or decreased during that time period. According to the Association of Peri-Operative Registered Nurses (AORN), 2008 Standards, Recommended Practices, and Guideline, the primary oxidizers in the operative room included oxygen, " Fire can occur when the oxygen level in the atmosphere rises above the level of ambient air (i.e., 21 %). Oxygen can escape into the air when the patient is given a mask. A level above 21% oxygen should be treated as an oxygen-enriched environment." The AORN strategies to manage risk of fire included the following: when using electrosurgical unit (ESU), to use the lowest power settings, do not use ESU near where oxygen, is flowing. During an Interview with Employee 3 on December 18, 2008 at 10:30 a.m., she stated that the was the first one who actually witnessed the first spark that was observed on Patient A's eyelash. She stated M.D. 2 started the procedure on the patient's right eye, and the bovie setting was set at 3 watts. However, when M.D. 2 started the procedure on the patient's left eye, a spark was observed. Employee 3 stated that M.D. 2 did not see the first spark, and he continued to use the bovie cauterizer on the patient. Employee 3 also stated that the bovie	E 347	including bony prominences, scar tissue, hairy surfaces, distal to a tourniquet or scar tissue, metal implants or tattoos. With respect to the "Active Electrode" it directs that the Active Electrode be visually inspected at the surgical field for any cord or hand piece damage, that the cord should be secured to the drapes using plastic towel clips, that "the electrode must be holstered when inactive" and specifically, to assure absolute compliance with the Policy and Procedure the policy stipulates and directs that "the scrub personnel are responsible to vigilantly monitor the holstering and report to management lack of cooperation by any member of the surgical team." (This portion of the Policy and Procedure cross-references the aforementioned "Fire Prevention in the Surgical Operating Room" again directing that when performing head and neck procedures utilizing an open oxygen delivery system, surgical team communication is essential.) This policy and procedure also addresses ESU use with patients with pace makers or internal cardio or other electrical implants as well as argon enhanced coagulation. Finally, provision is made in the Policy and Procedure for injury and malfunction reporting compliance. The Policy and Procedure further stipulates with respect to documentation that nursing documentation on the Peri-Operative Nursing Record should include: (1) Biomed ESU No(s); (2) Setting; (3) Area(s) of bad placement; and (4) Condition of skin prior to placement of pad and after removal.	

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E 347	Continued From Page 4 setting was set at 10 watts during the time the spark was observed. She stated that she did not hear any communication exchanged between M.D. 2 and /or M.D. 1 during the time the power setting for the bovie cauterizer was increased to 10 watts. A review of M.D. 2's operative report, dated December 9, 2008, indicated the following: Patient A was taken to the O.R. The eye was prepped and draped in the usual sterile fashion. Bovie cautery was used to make the skin incision and then the skin was removed using the cutting end cautery suction of the bovie blade., the right eye was started first and a nasal pack, which was protruding preoperatively was identified. By the use of a vascular clamp the gauze packing was excised (cut), with the bovie. Then the attention was on the left eye, the same thing was noted during the last nasal pack removal, there was a spark from the bovie and 7 bursts of fire came out of the patient's oxygen mask. A review of the plastic surgeon progress notes dated December 8, 2008, revealed that Patient A sustained 1% burn to mid face, mixed with 2nd and 3rd degrees burn involving the face, lips, around nasal passage with some singeing of the vibrissae, (scorching of the hairs inside the nose). She also sustained burns to the left corneal opacity (eyeball), and to the lower face. A review of the medical record revealed that Patient A was transferred to the Intensive care unit (ICU), where she remained for three days. On December 12, 2008, Patient A was subsequently discharged to a burn unit of general care acute hospital #2 for intense treatment of her facial burns.	E 347	Finally, provision is made in the Policy and Procedure for injury and malfunction reporting compliance. The responsibility for compliance with the Plan of Correction is that of the Vice President of Patient Care Services (present Margaret Pfeiffer, R.N., MSN). On December 23 and 24, 2008 the Hospital conducted an in-service and testing of all clinical staff to assure the these revised Policies and Procedures have been reviewed and to assure that all clinical staff to be present in the operating rooms have been tested with respect to their review and understanding of the Policies and Procedures to assure that all such persons who have not reviewed the Policies and Procedures or been tested may not be present in the operating room. A copy of the test administered to all such clinical staff regarding "Fire Prevention in the O.R. Post-Test" is marked as Exhibit "C." A description of the in-service for "Fire Prevention in the O.R." is marked Exhibit "D." Attached as Exhibit "E" are the sign-in sheets and test results for the clinical staff representing 100% compliance by all employees and travelers. As new employees are hired they are also required to attend an in-service and to take the "Fire Prevention in the O.R. Post-Test" before attending any patient in an operating room in the O.R. Testing following the in-service regarding "Fire Prevention in the O.R." is required annually of all employees and is conducted in December.	

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E 347	Continued From Page 5 The Operative/Procedure Report dated December 21, 2008, from acute hospital #2, indicated Patient A underwent a debridement of the left eye in order to assist healing of the cornea and to mitigate infection formation. On December 22, 2008, the Peri-Operative Record from acute hospital #2, revealed Patient A underwent debridement and autografting to the face with donor site from the patient's left side of her scalp. The facility's policy and procedure on Surgical Services, Use of Electrocautery Procedure, dated May 30, 2003, stipulated that proper care and handling of the electrocautery unit is essential to patient safety and should be used in a manner that minimized potential for injury. The procedure indicated the electrocautery unit is to be operated at the lowest possible power setting. In addition, the policy stipulated the power settings should be confirmed verbally between the user and the operator. This policy and procedure failure resulted in preventable burns to the middle and lower face, lips, nasal passage, and left corneal opacity (eyeball) of Patient 1 and subjected Patient A to be transferred to another hospital for intense treatment of the burns, where she underwent debridement of her left eye as well as debridement and autografting to the face.	E 347	No employee may be scheduled for the operating room before completing the test. All employees who are so scheduled are reviewed for compliance, by the Peri-Operative Educator and/or the O.R. Director. Further, to assure compliance with these Policies and Procedures, the "Surgical Safety Briefing" has been adopted and implemented to assure compliance with specific reference to the areas of concern as specified in the Statement of Deficiencies. Specifically, the Surgical Safety Briefing which must be accomplished before each surgical procedure, requires that in high risk procedures, such as a head and neck procedures involving open oxygen delivery, appropriate inquiry must be made and communicated and it is required that a written record, to be included in the patient's chart document that the surgeon, anesthesiologist and nursing team, have each reviewed and acknowledged specific areas of concern in electro cautery use in the presence of oxygen. A copy of the "Surgical Safety Briefing" which is included in each patient's medical chart is marked as Exhibit "F." This document was newly adopted and approved in January of 2009 by the Department of Surgery. It was implemented on February 23, 2009 and is presently in force. 50% of all surgical cases were reviewed on February 23, and 26, 2009 for briefing completeness. 100% compliance was noted by the Administrative Director of Peri-Operative Services (presently, Rebecca Salsson). 70 surgical cases per month for the ensuring four months will be reviewed for surgical briefing completeness by the	

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E 347	Continued From Page 6	E 347	Administrative Director of Peri-Operative Services. Thereafter, 70 surgical cases per quarter, for 1 year, will be reviewed for surgical briefing completeness. All audits/reviews are to be completed and reported quarterly to the quality council and annually to the Surgery Committee. Attached as Exhibit "G" is a document describing the "Surgical Safety Briefing Audit" and reflecting those audits completed on February 23 through February 26, 2009. As noted the audit was performed in collaboration with the Administrative Director of Peri-Operative Services, the Director of Surgery, the Peri-Operative Educator, and the Staff R.N. Also attached as Exhibit "H" is a copy of the "Surgical Safety Briefing Audit" conducted February 23 -26, 2009 with specific reference to the medical records numbers reviewed. Mandatory fire drills were completed by January 28, 2009 under the responsibility of the Administrative Director of Peri-Operative Services. Fire drills are to be performed annually for all shifts, with the responsibility, again, to be that of the Administrative Director for Peri-Operative Services. As set forth in Exhibit "I" titled "Fire Drill Evaluation" fire drills were conducted for the operating room staff on January 28 and 29, 2009. Different scenarios were created which involved role playing by staff members of the various job classifications and the participants were divided into three groups each led by a separate leader. Various scenarios were covered including a small controllable fire and a large fire requiring evacuation, as set forth in the exhibit. The feedback from all participants was positive and it was agreed that playing out the scenarios was realistic and relevant and helped educate the O.R. staff in the event of an actual fire.	

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E 347	Continued From Page 7	E 347	Finally, to minimize the possibility of any such event occuring in the future and to provide a process to facility prompt resolution of problems relating to patient care and, specifically, communication between health care professionals responsible for patient care and safety, a Policy and Procedure "Chain of Command/Problem Resolution" was revised effective January 29, 2009. A copy is attached as Exhibit "1." The Policy provides that in the event that a problem cannot be resolved between a health care associate and a treating physician such as a surgeon, chain of command will be activated up to and including the Medical Director, Section Chief or Department Chair. If such contac does not result in timely and sufficient resolution, the Chief Medical Officer or Medical Staff President is to be contacted. All of the above corrective actions have been implemented as of February 26, 2009.	

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