CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

POC reviewed / accepted 2/9/16

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050126	(X2) MULTIPLE CONSTRUCTION A BUILDING B WING	(X3) DATE SURVEY COMPLETED 08/21/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
VALLEY PRESBYTERIAN HOSPITAL	15107 Vanowen St, Van Nuys, CA 91405.4542 LOS ANGELES COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00262114 - Substantiated Representing the Department of Public Health: Surveyor ID # 28072, 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 1280.3: 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. Health and Safety Code Section 1276.3 (b) (1) The state department, shall promote safety by requiring that licensed health facilities that have surgical suites and procedural rooms provide information and training In fire and panic safety in oxygen rich environments, including equipment, safety, and emergency plans, as part of an orientation for new employees, and ongoing inservice training. (2) The licensed health facilities described in paragraph (1) shall use the fire safety guidelines in oxygen rich environments published by the		2016 FEB -8 PM 2:30 RECEIVED	HEALTH FACILITIES INSPECTION DIVISION ADMINISTRATION

Event ID:DQGB 11 1/15/2016 4:09:00PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVES SIGNATURE: SVP, Quality [signature] TITLE: SVP, Quality (X6) DATE: 2/5/16

By signing this document, I am acknowledging receipt of the entire citation packet, Pa Ws). 1 that 10

Any deficiency statement ending with an asterisk (1 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 far nursing homes, the findings above are disclosable go days following the date of survey whether or note plan of correction Is provided. For nursing homes, the above fndings 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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	Association of Operating Room Nurses or any other nationally recognized body or organization, and approved by the state department. 122 DIV 5 CHI ARTS-70213 Nursing Service Policies and Procedures. (a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service. (1) Policies and procedures which involve the medical staff shall be reviewed and approved by the medical staff prior to implementation. (2) Policies and procedures of other departments which contain requirements of the nursing services shall be reviewed and approved by the nursing service prior to implementation. (3) The nursing service shall review and revise policies and procedures every three years, or more often if necessary. (4) The hospital administration and the governing body shall review and approve all policies and procedures that relate to the nursing service every three years or more often, if necessary. (b) Policies and proceduresshall be based on current standards of nursing practice and shall be consistent with the nursing process which includes: assessment, nursing diagnosis, planning, intervention, evaluation, and, as circumstances require, patient advocacy. T22 DIV 5 CH1 ART3-70223 Surgical Service General Requirements (b) A committee of the medical staff shall be			

Event ID:DQGB11 1/15/2016 4:09:00PM

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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 review of Patient Is clinical record, review of the facility documents, and interviews with facility staff, the facility failed to implement its policies and procedures titled, "Skin Preparation" and "Fire Safety in an Oxygen Rich Environment," In addition, the operating room staff failed to follow the manufacturer's recommendation on the use of an alcohol-based antiseptic solution and the Association of periOperative Registered Nurses (AORN) guidelines on how to minimize the risk of a surgical fire and patient burn injury. The facility's failure resulted in a fire in the operating room during the surgical procedure being performed on Patient 1. According to the operative report dated February 8, 2011, Patient 1 sustained burns on her right earlobe, right lower neck and right chest wail, and 3 or 4 areas on the left upper extremity, all possible second-degree bums.

Findings:

On August 21, 2012, anunannounced visit was made to the facility to investigate an entity reported incident regarding a patient whose skin caught on fire during a procedure in the operating room,

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	resulting in the patient sustaining burns to the right ear, neck, and chest. The clinical record for Patient 1 was reviewed on August 21, 2012, at 10:05 a.m. The Patient Registration Form indicated Patient 1 was admitted to the facility on February 4, 2011 at 2:16 p.m. The History and Physical dated February 4, 2011, indicated Patient 1 was admitted to the facility for abdominal wound infection. The document titled, "Consultation Record" dated February 7, 2011, indicated Patient 1 had headache, right side facial numbness, and the patient was scheduled for a temporal artery (blood vessels to the head) biopsy (removal and examination of tissue from the living body) to rule out temporal al'tents(inflammation and damage to the blood vessels that supply blood to the head, neck, upper body and arms) on February 8, 2011. A review of the printout of the "Operative Nursing Diagnosis Screens" dated February 8, 2011 indicated under "Potential for injury related to fire in An oxygenen rich environment...Intervention ...C. Allow prep solution to dry before draping", the answer documented was "yes". Under "D. Ensure that drapes are not tented so that 02 [oxygen] collects under them", the answer was documented as "yes". Under "J. Prevent the use of 100% 02 in the presence of ESU [electrosurgical unit- a device used to cut tissue and or stop surgical bleeding by coagulating the blood during surgery] or laser", the answer documented was "Yes", There was no documentation the skin-prepped area was		An RCA was conducted on February 14, 2011. As a result the "Fire Safety in an Oxygen Rich Environment" and "Skin Preparation" policies were combined into one policy "Fire Safety and Fire Risk Assessment" approved 10/28/14 (Attachment A). As a result of this deficiency the policy is being updated to include: (Attachment B) • Visualize and document flammable prepping solutions are completely dry and fumes has dissipated before applying surgical drapes. • Surgeon to notify Anestesiologist prior to bovie use. • Follow manufacture's recommendations for use of the skin prep. To be completed and approved by:	3/31/16

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	inspected to confirm that the skin cleaned with the alcohol-based solution was dry prior to draping over the area. There was no documentation of how long the drying time was. However, the document indicated the surgical skin was prepared using the solution "Cholora Prep" (a flammable antiseptic solution) to the patient's right face by Registered Nurse (RN) 1. The Operative Record dated February 8, 2011 indicated Patient 1 needed a temporal artery biopsy on the right side to rule out temporal arthritis. The record indicated "a tenting drape was placed over the medial face to cover her eyebrow, eye, and mouth. She was wearing a facemask below the tenting drape. At this point, she was prepped with ChloraPrep (26 ml) and after several minutes dry towels wereplaced, covering her ear, the tenting drape, her hair ... The second time the Boyle (ESU) was used, all of a sudden a spark was started and fire was visualized." The operative report indicated Patient 1 sustained burns on her right earlobe, right lower neck and right chest wall, and 3 or 4 areas to the left upper extremity, ail possible second-degree burns. The AnesthesiaRecord dated February 8, 2011, indicated the type of anesthesia used on Patient 1 was "MAC" (Monitored Anesthesia Care - uses sedatives and other agents, but the dosage is low enough that patients remain responsive and breath without assistance). The record indicated Patient 1 was administered oxygen via face mask, starting at four (4) liters per minute (1pm) oxygen flow at 1 p.m, The record indicated the oxygen flow was increased		The Patient's Plan of Care for Operating room patients will be revised for documentation of: • Visualization of flammable prepping solutions are completely dry and fumes have dissipated before applying surgical drapes. • Documentation of dry time. To be completed by:	2/29/16

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	to eight (8) lpm at 1:30 p.m. The record indicated the "incident- 1344 (1:34 p.m.)" "Incident - fire on the field. Airway was secured for safety. Oxygen (02) turned off immediately." "FM (face mask) was used - FM was not burned at all ..." The document titled "Consultation Record" dated February 11, 2011, indicated Patient 1 had an approximately 5% total body surface area burns with deep partial thickness burns, with bullae (a blister more than 5 mm (about 3/16 inch) in diameter with thin walls that is full of fluid) of her left shoulder and upper chest, neck, and right ear, anteriorly and posteriorly. There is some possible full-thickness (third degree bums) areas but they appear to be small." Patient 1 "will be followed up at a Bum Center."Patient 1 "may need to have some formal cleaning of the wound with some anesthesia because it is really too painful to clean it with her awake." The facility policy and procedure titled "Skin Preparation" Number NRO 01-175, dated July 2008, indicated not to allow the prep solution to pool around or underneath the patient or under any equipment on the patient. Allow prep solutions ample contact time before applying the sterile drapes. If using flammable antiseptic solutions, allow time for complete evaporation of the solution before beginningsurgery, to decrease the risk of fire. However, the policy did notaddress the assessment and documentation of wait (dwell) time needed to ensure the flammable antiseptic solution was dry. The policy did not address the manufacturer's recommendations for the use of the			

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flammable antiseptic solution.

The facility policy titled "Fire Safety in an Oxygen Rich Environment" dated June 2008, stipulated the Eiectrosurgical unit generator shall not be used in the presence of high concentration of oxygen or flammable agents, such as alcohol or tincture-basedagents. The policy indicated not to allowthe prep solution to pool. Allow the prep solution to dry before using the electro cautery unit. Ensure that oxygen does not become trapped under the drapes. When oxygen is delivered under the drapes, it can create an oxygen enriched atmosphere. Tent the drapes to vent the gas.

The 26 milliliter (ml) applicator ChloraPrep label was reviewed. The label stated the active ingredients of the solution were chlorhexidine gluconate 2% and 70% Isopropyl alcohol. The label had, In bold letters, a warning to prep carefully to reduce the risk of fires. The label indicated "do not use the 26-mL applicator for head and neck surgery. Do not use on an area smaller than 8.4 in (inches)by 8.4 in. Use small applicator instead. Solution containsalcohol and gives off flammable vapors. Do not drape or use ignition source (e.g. cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair), Avoid getting solution into hairy areas. Wet hair is flammable. Hair may take up to 1 hour to dry. Remove wet materials from prep area."

During an interview with Administration Staff

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	(Admin) 1 on August 21, 2012, at 9:55 a.m., she stated Patient 1 was "draped, ChloraPrep used on face as instructed by MD (physician). Time frame to dry - 3 minutes- patient given oxygen via mask." "It was a perfect triangle of the 02, Bovie spark and ChloraPrep use." During an interview with the Chief Anesthesiologist on August 21, 2012, at 11;50 a.m., the Chief Anesthesiologist stated the anesthesiologists received a case presentation regarding the incident. General fire prevention, with a focus mainly on oxygen, tenting, use of chlorhexidine, and the drying time of chlorhexidine were discussed. The surgeon involved in the operating room fire case refused to be interviewed by the evaluator during the investigation. According to Association of per] Ope rative Registered Nurses (AORN) guidelines, if a flammable prep agents are used, additional precautions should be taken to minimize the risk of a surgical fire and patient burn injury. The flammable prep agent should be packaged in small quantities appropriate for a single application or be -prepackaged in a unit dose to minimize the risk of soaking material adjacent to the prepped area and limits the amount left over for disposal. The Director of Surgery Services was interviewed on August 21, 2012, at 12:04 p.m. He stated the 26-m1 container of ChloraPrep was the only size used in the facility for pre-surgical skin preparations.		The facility has the 3ml and 24ml ChloraPrep applicators available. Completion Date:	Ongoing

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SUMMARY STATEMENT OF DEFICIENCIES:

During a concurrent interview with RN 1, she stated she estimated the drying time for the ChloraPrep was 10 minutes before sterile drapes were placed on top of the site cleaned. She stated the site she cleaned was close to Patient 1's hair, and "just the edge of the hair got wet with ChloraPrep."RN 1 stated she did not document the drying time for the ChloraPrep. RN1 stated "I was not aware that there was something in the label that said that do not use 26-m1 in head and neck surgery and drying time up to 1 hour in hair."

The cautery machine used duringthe procedure was sequestered and examined. The "Examination of Electrosurgical Unit Repot dated March 10, 2011, by a bio-medical consulting company, indicated "there is no indication that the electrosurgical units used in these cases malfunctioned. In the case of the fire and patient burn, the spark was most likely caused by the generator energized before full contact with tissue was achieved and arcing (an electrical breakdown of a gas that produces an ongoing plasma discharge, resulting from a current through normally nonconductive media such as air) occurred. This arc ignited the adjacent drape, and was accelerated by the presence of oxygen and anesthetic vapor mixture which escaped from the mask used or the patient."

According to the Association of periOperative Registered Nurses(AORN), "electro-surgeryshould not be used in an oxygen-enriched environment. An oxygen-enriched environment lowers the temperature and energy at which fuels will ignite.

PROVIDERS PLAN OF CORRECTION:

Education on Fire Safety/Prevention and ChloraPrep use was completed for Operating Room staff on March 31, 2011.

Re-education to Operating Room staff will include:

- Alcohol-based prep in-service with competency checklist (Attachment C)
  To be completed by: 2/29/16
- Fire drill with mock evacuation scenario.
  To be completed by: 2/29/16
- Fire Safety in the Operating room with a competency checklist.
  To be completed by: 2/29/16

Anesthesia Department to view video "Prevention and Management of Operating Room Fires" (Attachment D). All anesthesia providers will sign a verification of viewing the video and understanding (Attachment E).
To be completed by: 2/29/16

Surgery Committee to view video "Prevention and Management of Operating Room Fires" with signed verification (Attachment D & E).
To be completed by: 3/10/16

Annual education on Fire Safety/Prevention, alcohol-based prep, and fire drills will be done annually during the months of February and March.
Completed by: 3/31/16 & ongoing

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	Fires, including airway fires, have resulted from the active electrode sparking in the presence of concentratedoxygen. The lowest possible oxygen concentration that provides adequate patient oxygen saturation should be used. Mixing oxygen with nonflammable gases such as medical air reduces the risk of fire. Surgical drapes should be arranged to minimize the buildup of oxidizers (e.g., oxygen and nitrous oxide)under the drapes, to allow air circulation, and to dilute theadditional oxygen. The active electrode should be used as far from the oxygen source as possible," (http://aornstandards.org) This facility failed toprevent thedeficiency(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 1280.3(g).		The Director of Quality/Risk Management is responsible for monitoring the corrective action plans. 30 charts will be audited monthly for documentation of: • Visualization of prepping solutions are completely dry and fumes have dissipated before applying drapes. • Documentation of dry time • Documentation of Surgical Risk assessment. Audits will be conducted until a 100% compliance is reach for 6 months.	ongoing