The following reflects the findings of the Department of Public Health during an inspection visit:

Complaint Intake Number:
CA0224833 - Substantiated

Representing the Department of Public Health:
Surveyor ID # 16499, 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.

REGULATION VIOLATION:
Title 22 70223 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 record review, the facility

INITIAL COMMENTS:
St. Mary Medical Center ("SMMC") promotes personal and professional development, accountability, innovation, teamwork, and a commitment to quality (SMMC Core Value of Excellence). SMMC is committed to adhering to the requirements of the Medicare Conditions of Participation and all other relevant Federal and State laws. This document is submitted as evidence of correction of the deficiencies identified for entity reported incident number CA0224833 during the investigation which was completed on April 8, 2010.

Preparation and/or execution of this Plan of Correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth on the Statement of Deficiencies. The Plan of Correction is prepared and executed solely because it is required by provisions of federal and state law. None of the actions taken by SMMC pursuant to its Plan of Correction should be considered an admission that a deficiency existed or that additional measures should have been in place at the time of the survey. The provider submits this Plan of Correction with the intention that it is inadmissible by any third party in any civil or criminal action or proceedings against the provider, its employees, agents, officers, directors, or shareholders. This Plan of Correction is submitted to meet requirements established by state and federal law.
Even though the patient was receiving oxygen via an oxygen cannula, the machine was taken out of service and checked by the biomedical maintenance staff on 2010. The machine checked out with no problems noted.

During an interview with the operating room (OR) manager on April 7, 2010 at 9:20 AM, she stated she was not in the OR for the procedure and when she and the risk manager got there, the patient was already bandaged and treated. No pictures were taken. The surgical staff told them that as soon as the Bovie was engaged, there was a flash fire.

During an interview with the Risk Manager, on April 7, 2010 at 9:20 AM, she stated that the Bovie machine was taken out of service and checked by the biomedical maintenance staff on 2010. The machine checked out with no problems noted. She also stated that Bovie had previously checked the machine in January 2010 and it checked out with no problems noted. She stated, "The physician did not let the anesthesiologist know that he was going to engage the Bovie." She also stated that the "Surgical Fires, Prevention Of Policy and Procedure (P&P) failed to follow their Policy and Procedure for Surgical Fire Prevention and failed to ensure Patient A's safety during a surgical procedure on the patient's face.

FINDINGS
Patient A received 1st and 2nd degree burns on the face and upper lip on 2010, when the physician engaged the Bovie cautery (a device used for burning and/or cutting the skin or other tissues by means of heat and electric current) while the patient was receiving oxygen via cannula. The burn was a flash fire on the patient's right cheek and upper lip.

During an interview with the Operating Room (OR) manager on April 7, 2010 at 9:20 AM, she stated she was not in the OR for the procedure and when she and the risk manager got there, the patient was already bandaged and treated. No pictures were taken. The surgical staff told them that as soon as the Bovie was engaged, there was a flash fire.

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The following plan of correction details the actions undertaken by SMMC to correct such deficiency listed on the State 2307 and provides evidence of compliance to the SMMC Policy and Procedure titled "Surgical Fires, Prevention of" and to ensure patient safety.

**IMMEDIATE ACTIONS TAKEN:**
Upon cauterization of the basal cell on the right side of the nose, a spark was noticed and then a flame around Patient A's cheek (approximately 1/4 inch). Immediately, the surgeon instructed the anesthesiologist to turn off the O2 (oxygen). The surgeon removed the nasal cannula, placed a wet sponge on the operating site, and the circulating RN pulled off all the drapes. The surgeon and anesthesiologist performed an assessment of the burned area.

**TITLE 22 70221 SURGICAL SERVICE GENERAL REQUIREMENTS:**
SMMC has an effective governing body legally responsible for the conduct of the hospital as an institution and ensures that medical staff are held responsible for maintaining quality provided to patients, ensures that Quality Assurance Performance Improvement (QAPI) programs focus on prevention of surgical errors, and ensures that surgical care services are achieved at the highest standards of medical practice and patient care. SMMC has established policies and procedures to prevent surgical fires, specifically the Policy and Procedure titled "Surgical Fires, Prevention of" effective March 24, 2010.
Instructs surgical staff to turn off the oxygen for 1 minute prior to engaging the Bovie. Surgical staff did not follow the facility P&P.

Review of Patient A's clinical record on April 7, 2010, noted Patient A, a 68 year old female, had minor surgery on her nose to remove a basal cell carcinoma (skin cancer) on March 28, 2010. Surgical notes showed a detailed timeline of the event, documenting that the anesthesiologist turned off the oxygen after the flame appeared, and the circulating nurse removed the sterile drapes.

During an interview with the plastic surgeon on April 7, 2010, he stated that "he did the wound care himself for approximately 2 weeks". He also stated that the patient was "still applying ointment to an area about the size of the tip of an eraser". When asked if he had taken pictures, he stated "No but the patient did, and she sent them to me".

During an interview on April 8, 2010, the anesthesiologist stated that in this case, "no warning was given that the Bovie was going to be used. The Bovie was not holstered, the physician picked it up and began using it", without letting the surgical team know. The anesthesiologist stated that the surgical team did not follow the facility P&P.

Review of the facility P&P titled "Surgical Fires, Prevention Of " dated May 2009, under Use of Electrocautery, noted: "stop supplemental oxygen at least one minute before and during use of the electrocautery".

**Title 22 70223 Surgical Service General Requirements** (Continued): Subsequently, Patient A was transferred from OR21 to Post Anesthesia Care Unit (PACU). The surgeon and anesthesiologist notified the patient and family about the incident. Orders for Arterial Blood Gases (ABG) and Carbon Monoxide tests were ordered by the anesthesiologist; carbon monoxide results were negative and Anesthesiologist immediately informed the patient and family members with results.

On February 26, 2010, upon discovery of the event, SMHC Risk Management immediately initiated an investigation into this event in collaboration with the Surgical Services Leadership Team to ensure immediate processes were implemented for the safety of other patients that could be affected by the same outcome.

On February 26, 2010, the Interim Perioperative Services Director initiated 1:1 verbal education to the Surgical Services staff members to raise awareness of the risk of surgical fires and to reinforce the policy and procedure titled "Surgical Fires, Prevention of". During this education, the staff members were made aware of the requirements when electrocautery is used with an open oxygen delivery system to stop supplemental oxygen at least one minute before and during cautery use.

On February 28, 2010, an immediate containment strategy was initiated to ensure the five (5) steps listed below are followed when electrocautery is used in an open oxygen delivery system during cases that include head/neck surgeries:

<table>
<thead>
<tr>
<th>Event ID: GCN911</th>
<th>5/22/2014</th>
<th>3:16:05PM</th>
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During a telephone interview with the patient, on April 9, 2010 at 2:30 PM, she stated the physician told her "it was almost a 3rd degree burn". She stated that it was healing nicely, the wound was still discolored but closed, and then this past week, it started again, about the size of a quarter coin. It was originally covered by a 4 x 4 gauze pad, and you could see the swelling involved. The patient sent pictures taken on April 9, 2010 and April 11, 2010, showing the deep 2nd degree burn.

The facility’s failure to prevent the surgical fire on the patient’s face has caused, or is likely to cause, serious injury or death to the patient.

The 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(e).

| TITLE 22 70223 SURGICAL SERVICE GENERAL REQUIREMENTS (Continued): |
| 1. The surgeon announces aloud to the anesthesiologist the intent to "energize the cautery". |
| 2. The anesthesiologist will acknowledge and announce aloud "the oxygen is being turned off". |
| 3. The anesthesiologist will give the surgeon notification when it is safe to proceed (i.e., after one minute of oxygen being turned off). |
| 4. Thereafter, the surgeon will notify the anesthesiologist when finished with the cautery and. |
| 5. The anesthesiologist will notify the surgeon and the OR nursing staff that oxygen has commenced. |

On March 5, 2010, the Vice President of Medical Affairs (VPMA) reviewed the case involving Patient "A" to the Anesthesia Department and on March 17, 2010 to the Surgery Department for Peer Review for Initial screening. The case was reviewed and final disposition obtained with a recommendation to follow up with a presentation to the Medical Executive Committee (MEC) during the next scheduled meeting on May 11, 2010.

On March 20, 2010, the Interim Director of Perioperative Services Department reviewed and revised the Policy and Procedure titled "Surgical fires: Prevention of". Revisions included "when electro-cautery is used with an open oxygen delivery system, to stop supplemental oxygen at least one minute before and during cautery use", to ensure this policy meets the guidelines from Association of Perioperative Registered Nurses (AORN) and American Society of Anesthesiologists (AOA).
During a telephone interview with the patient, on April 9, 2010 at 2:30 PM, she stated the physician told her "It was almost a 3rd degree burn." She stated that it was healing nicely, the wound was still discolored but closed, and this past week it blistered again, about the size of a quarter coin. It was originally "covered by a 4 x 4 gauze pad, and you could see the swelling involved". The patient sent pictures taken on March 12, 2010 and April 9, 2010, showing the deep 2nd degree burn.

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.

This facility's failure to prevent the surgical fire on the patient's face 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 and Safety Code Section 1280.1(c).

On May 4, 2010, the Chief of Surgery (COS) and Chief of Anesthesiology (COA) developed and sent a memorandum to the anesthesiologists and surgeons including OB/GYN reinforcing the importance of implementing fire precautions in the OR setting.
During a telephone interview with the patient, on April 9, 2010 at 2:30 PM, she stated the physician told her it was almost a 3rd degree burn. She stated that it was healing nicely, the wound was still discolored but closed, and then this past week, it blistered again, about the size of a quarter coin. It was originally "covered by a 4 x 4 gauze pad, and you could see the swelling involved". The patient sent pictures taken on March 12, 2010 and April 9, 2010, showing the deep 2nd degree burn.

The facility's failure to prevent the surgical fire on the patient's face has caused, or is likely to cause, serious injury or death to 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).

On July 19, 2010, the Chief of Anesthesia, who was directly involved in the care of Patient 'A', provided an in-service to the Anesthesia Department members present with regards to the recent case involving the use of "Bovie" in which a patient suffered a burn during the surgical procedure. The policy and procedure titled "Surgical Fires, Prevention of" was presented and every member was requested to adhere to such policy.
During a telephone interview with the patient, on April 9, 2010 at 2:30 PM, she stated the physician told her "it was almost a 3rd degree burn". She stated that it was healing nicely, the wound was still discolored but closed, and then this past week, it blistered again, about the size of a quarter coin. It was originally "covered by a 4 x 4 gauze pad, and you could see the swelling involved". The patient sent pictures taken on March 12, 2010 and April 9, 2010, showing the deep 2nd degree burn.

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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).

### QUALITY ASSURANCE PERFORMANCE IMPROVEMENT MONITORING:
The Interim Director of Perioperative Services Department or designee performed monthly chart audits of identified cases involving head and neck surgeries that required the delivery of supplemental oxygen. This was done to ensure the established process as approved by the Medical Executive Committee was followed as evidenced by the Anesthesiologist and Surgeon documentation.

The Interim Director of Perioperative Services Department or designee documented the results of such audits for at least three (3) consecutive months and until 100% compliance was achieved. Thereafter, Performance Improvement Indicators were monitored on a periodic basis to ensure ongoing compliance/sustainment.
During a telephone interview with the patient, on April 9, 2010 at 2:30 PM, she stated the physician told her "it was almost a 3rd degree burn". She stated that it was healing nicely, the wound was still discolored but closed, and then this past week, it blistered again, about the size of a quarter coin. It was originally "covered by a 4 X 4 gauze pad, and you could see the swelling involved". The patient sent pictures taken on March 12, 2010 and April 9, 2010, showing the deep 2nd degree burn.

The facility's failure to prevent the surgical fire on the patient's face has caused, or is likely to cause, serious injury or death to 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).