The following reflects the findings of the California Department of Public Health during the investigation of an entity reported incident.

Intake #: CA00187812

Representing the Department of Public Health:

REGULATION VIOLATION:
Title 22 70333 Autoclaves and Sterilizers.
(c) Written procedures shall be developed, maintained and available to personnel responsible for sterilization of supplies and equipment to include, but are not limited to the following:

1. Time, temperature and pressure for sterilizing the various bundle, packs, dressings, instruments solutions, etc.
2. Cleaning, packaging, string and issuance of supplies and equipment.
3. Dating and outdating of materials sterilized.
4. Loading of the sterilizer.
5. Daily checking of recording and indicating thermometers and filing for one year of recording thermometer charts.
6. Monthly bacteriological test, the bacterial organism used and filing for one year of the test results.
7. Length of aeration time for materials gas-sterilized.

Corrective Action:
Education provided to the Registered Nurses and Operating Room Technicians of the involved department. The in-services were initiated on 11/20/08. Education consisted of two acceptable means by which flash sterilized instruments are to be cooled prior to use. The flash sterilization policy was reviewed during in-services and additional changes were made to the policy following staff input from completed education.

Event ID:686111
12/22/2009 2:04:32PM

LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

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 that documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.
Based on interviews and record review, the facility failed to develop a written procedure for flash sterilization that included procedures to protect patients from burns due to hot instruments. This failure resulted in Patient 1 developing a third degree burn on the left calf from a flash sterilized instrument (triangle) requiring skin grafting of the burned area.

FINDINGS:
On 11/3/08 at 1:00 PM a visit was made to the facility to investigate a self reported facility incident regarding a patient receiving a burn during surgery performed on [Redacted].

Review on 1/21/09 of Patient 1's record, revealed that Patient 1 was [Redacted] years of age and was admitted on [Redacted] for outpatient surgery to remove orthopedic hardware from the left knee. Patient 1 had previous surgery of the left knee following a fracture of the knee cap.

In an interview on 1/21/09 at 1:30 PM, with the Department Administrator for Operative Services regarding the incident involving Patient 1, she stated that a "Triangle" was used to position Patient 1's knee for surgery. She stated that a triangle was a positioning device to hold the knee in the operative position. The patient's leg was put on it so that the knee was in a bent position. She further stated that the operating room staff "flash sterilized" (a procedure to sterilize instruments

In addition, additional "Triangles" (positioning devices used on "patient 1" during surgery to hold the knee in the operative position) were purchased and placed into service.

The Flash Sterilization Policy and Procedure was revised 12/09 and 1/6/10 to directly address the procedures for cooling of flash sterilized instruments. This revised policy will be presented to the Registered Nurses and Operating Technicians of the involved department in January 2010. Once in-services are completed, these staff members will sign an attestation form validating their understanding and commitment to the department's policy and procedure on "Flash Sterilization".

Responsible Party:
Department Administrator of Operating Room
Director of Perioperative Services
Monitoring Process:
Daily flash sterilization logs are posted at each autoclave. These are collected, monitored and reviewed by the Assistant Department Administrator and in their absence, the Department Administrator. A flash sterilization report is generated monthly that captures the reasons that instrument(s) are being flashed sterilized. Any noted trends on this report are addressed. This report is reported monthly to Infection Control Committee of the hospital. No issues have been identified with flashing of triangles.

Monitoring logs for the past year reflect no triangles have been flashed. They are all processed through the Central Sterilization Department.
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deep burns. There were three areas of
deep burns measuring 2 x 3 cm, 3x3 cm, and
1.5 x 1.5 cm. The rest of the burn involved
posterior (behind) calf and behind the knee,
measuring 17 x 9 cm. The physician further
documented, "If the deeper burns don't
improve, I have told him the possible need to
excise (cut out) burns and skin graft."

Review of an operative note dated
revealed that Patient 1 had skin grafting to the
3rd degree (burn through the skin into deeper
tissue) burn to the left posterior calf and
behind the knee. Some of the risks of the
surgery as explained to Patient 1 included:
bleeding, infection, poor scarring, failure of
graft, and risk of contracture (an abnormal,
usually permanent condition of a joint
characterized by being bent and fixed. May be
caused by loss of elasticity of the skin caused
by extensive scarring) over the long term given
the burn extends into popliteal fossa (back of
the knee).

Review of the facility policy and procedure
titled Flash Sterilization effective date 9/94 and
last revised 7/08 under section 3 Transporting
items to Sterile Field, indicated "Use towels or
other protective materials to protect against
burns from hot items, trays or containers."

There was no procedure listed on how to
protect a patient from burns or on how to
determine if the flash sterilized instruments
were cool enough to be used on a patient.
The facility's failure to develop a written procedure for flash sterilization that included procedures to protect patients from burns due to hot instruments is a deficiency that 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).