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
	050320	A. BUILDING _____ B. WING _____	03/16/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Highland Hospital	**1411 E 31st Street, Oakland, CA 94602-1018 ALAMEDA COUNTY**

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: No complaints found - Substantiated Representing the Department of Public Health: Surveyor ID # 2319, 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(g): 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. A Relicensure Survey was conducted on 03/13/2017 to 03/16/17. The state regulation violated: California Code of Regulations, Title 22, Section 70739(a) § 70739. Infection Control Program. (a) A written hospital infection control program for the surveillance, prevention and control of infections shall be adopted and implemented. The program shall include policies and procedures that: (1) Define and require methods to handle all patients, all blood and body fluids and all materials that are soiled with blood and/or body fluids from all			

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

By signing this document, I am acknowledging receipt of the entire citation packet, *Page(s). 1 thru 20*

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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	patients. The methods prescribed shall be designed to reduce the risk of transmission of potentially infectious etiologic agents from patient to patient and between patient and healthcare worker. The methods shall include handwashing, the use of gloves, the use of other barriers, the handling of needles/sharps and the disposal of materials that are soiled with or contain blood and/or body fluids. (2) Define practices to reduce the risk of transmission of airborne infectious etiologic agents including tuberculosis and addressing the assignment of rooms and/or roommates. (3) Provide for and document the education of all personnel. Based on observation, interview, and record review, the hospital failed to ensure its Infection Control Program's policies and procedures for surveillance, prevention and control of infection, were effectively evaluated and implemented in its surgical and perioperative departments, as evidenced by: 1. The decontamination room (the process of cleansing an object or substance to remove contaminants such as micro-organisms or hazardous materials, including chemicals, radioactive substances, and infectious diseases) was not climate controlled. 2. No evidence was provided to demonstrate the hospital's decontamination and sterile processing rooms were routinely and terminally cleaned (a cleaning method used in healthcare environments to control the spread of infections) or organized in a			

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	manner, which prevented the potential for cross contamination. 3. Several reusable patient equipment systems (Neptune 2 Rover and a Dornoch - reusable suction system used during surgical procedures, to collect surgical waste) were not cleaned according to manufacture instructions and the waste was not disposed according to manufacture instructions. 4. Soiled surgical instruments were not pre-cleaned according to infection control standards and hospital policy after being used during surgical procedures and were not cleaned and disinfected according to infection control standards. 5. During two separate observations, while staff cleaned and disinfected soiled instruments, various concerns were identified while the staff cleaned instruments and scopes. In addition, sterilization containers (closed containers used to hold medical instruments during sterilization and preserve their sterile state until they are removed for use) were not cleaned in between use. 6. The procedures for cleaning, disinfection, and sterilization of endoscopes (a camera on a flexible tube used to look inside the body through a surgically created, or naturally occurring body opening.), and maintenance of the endoscope cleaning equipment (Medivator) were not standardized and did not follow infection control standards. 7. There was no comprehensive Quality Assurance and Safety Program for all aspects of endoscopy procedures. (Endoscopy is the process of looking inside the body with an endoscope.) Within the meaning of Health and Safety Code			

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	§1280.3 (g), this failure constituted an immediate jeopardy (IJ), because of the potential for cross contamination and spread of bacteria and other microorganisms which could result in surgical patients contracting serious infectious diseases. Therefore the above violations caused or were likely to cause, serious injury or death to patients who had surgical procedures. Findings: 1. During an interview conducted on 3/13/17 at 9:45 AM, the Infection Control Preventionist (ICP) stated the hospital followed the nationally recognized infection control standards from Association of periOperative Registered Nurses (AORN), Association of Advanced Medical Instrumentation (AAMI), Centers for Disease Control (CDC) and manufacture guidelines. On 3/13/17 at 11:25 AM, during an interview and a tour of the decontamination room, accompanied by ICP, Assistant Director of Nursing (ADON) and Director of Perioperative Services (APOS). Immediately upon entering the room, the following concerns were identified: a. The room was warm and had a strong odor. b. No temperature or humidity gauges were observed. The APOS, who confirmed the room was warm and did have an odor, stated they did not monitor the temperature or humidity in the decontamination room and did not have temperature or humidity gauges.			

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	Review of hospital policy, titled "Sterile Processing: Principles of Cleaning & Decontamination," revised 1/2013, "3. Environmental Design and Controls, c. The temperature should be regulated between 18°C and 22°C (64°F and 72°F)...A low temperature also helps inhibit the growth of microorganisms. d. Relative humidity should range from 35% to 70%. According to the AORN's (nationally recognized infection control standards the hospital follows) Guidelines for Perioperative Practice, 2015 Edition, Guideline for Sterilization: bacteria and fungi thrive at warm temperatures, whereas cooler temperatures may impede bacterial and fungal growth in the decontamination area. According to CDC, "Guideline for Disinfection and Sterilization in Healthcare Facilities", relative humidity should be 30-60% in all works areas except sterile storage, where the relative humidity should not exceed 70%. 2. An interview conducted, on 3/13/17 at 9:45 AM, with the ICP, he stated the hospital followed the nationally recognized infection control standards from AORN, AAMI, CDC and manufacture guidelines. On 3/13/17 from 11:25 AM to 12:30 PM, during an interview and tour of the decontamination room, the following concerns were identified: a. Clean and dirty items were stored adjacent to one another. b. Multiple soiled surgical instruments/equipment			

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	and surgical processing trays were piled on top of a worktable. c. A worktable used for holding soiled surgical instruments was cracked in various areas, exposing a brownish/yellow porous shedding type of material. d. Soiled surgical instruments in a tray were left in a sink. c. The floor had multiple brown, black and gray fuzzy particles. d. Sink counters and faucets had white and green crusty matter. e. The Neptune (a patient suction system equipment used for collecting surgical waste) floor docking unit had black and brown matter. f. The Neptune hose connected into a hopper and above the water level, had dried blood. g. Blood was found at the bottom and around the hopper basin. h. There was no clear delineation between clean and dirty items. i. A soiled brush used for cleaning a hopper (a wall mounted sink/toilet like unit with continuous flushing rim and bowl for the disposal of liquid and solid waste) in the decontamination room was stored with brushes used to clean/scrub surgical instruments and flexible scopes. j. A metal cart containing clean items/supplies had white crusty matter in various areas. Also identified was red dried matter. The Surgical Processing Technician (SPT) 1 stated the red matter on the Neptune hose and the hopper was blood and there was not a routine cleaning schedule. SPT 1 also stated the red matter on the metal cart, containing clean supplies, was blood.			

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	During interviews with the ICP and APOS, they agreed that the decontamination room was not cleaned and there was no clear separation of clean and dirty items. A request was made to produce documents to show the room was cleaned on a regular basis and to show that it was terminally cleaned. Documents were not produced throughout the survey and APOS stated they did not have any logs or cleaning schedules. Review of hospital policy, titled "Sterile Processing: Principles of Cleaning & Decontamination," revised 1/2013, states "1. Definitions. a. Cleaning - the removal of all visible and non-visible soil, and any other foreign material from the medical device being reprocessed. Instruments must be thoroughly cleaned and rinsed from subsequent reprocessing steps to be effective." Review of hospital policy, titled "Sterile Processing: Principles of Cleaning & Decontamination," revised 1/2013, states "4. Housekeeping Concerns, b. Spills should be spot-cleaned immediately. c. Floors should be cleaned and disinfected daily. e. Tools such as mops use (sic) to clean in the decontamination area should not be used in other areas of the department." According to CDC guidelines, sterile supplies should be stored in a manner, which prevents contamination, there should be a clear separation of			

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	sterile items and dirty items, and there must be separate clean/dirty rooms or the designated utility room must flow from clean to dirty. AORN defines terminal cleaning as "thorough environmental cleaning that is performed at the end of each day when the area is being used." Both AORN and AAMI ST79 recommended sterile processing be terminally cleaned the same as the operating, delivery, and invasive procedure rooms. AAMI ST79 (Section 3.4) indicates the best practice is to provide separate housekeeping facilities for the decontamination and clean areas to avoid transferring contaminates from "dirty to clean" areas. AORN further stipulates, "scheduled cleaning is a cleaning schedule that defines areas and equipment that should be cleaned on a regular (e.g., weekly, monthly) basis. AORN recommends terminal cleaning and disinfection of the sterile processing areas "be performed daily when the areas are being used." Terminal cleaning should not be performed when personnel are actively de-contaminating instruments. Cleaning should progress from cleanest to dirtiest areas. AORN recommends (Recommendation V) a schedule for cleaning the following: clean and soiled storage areas, storage cabinets, sterile storage area, aerators on faucets should be cleaned and disinfected on a routine basis... According to AAMI ST79: "Walls, storage shelves, and air intake and return ducts should be cleaned on a regularly scheduled basis and more often if needed. Stained ceiling tiles should be replaced, and any leaks causing the stains should be			

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	repaired. Lighting fixtures or covers should be cleaned at least once every 6 months ..." According to CDC, "Guideline for Disinfection and Sterilization in Healthcare Facilities", Cleaning reduces the bioburden and removes foreign material (i.e., organic residue and inorganic salts) that interferes with the sterilization process by acting as a barrier to the sterilization agent. Surgical instruments are generally presoaked or prerinsed to prevent drying of blood and tissue. Precleaning in patient-care areas may be needed on items that are heavily soiled with feces, sputum, blood, or other material (all are bioburden materials). Items sent to central processing without removing gross soil may be difficult to clean because of dried secretions and excretions. Cleaning and decontamination should be done as soon as possible after items have been used. 3. On 3/14/17 at 12:30 PM, during an observation a Certified Nurse Assistant's (CNA's), demonstrated the process for cleaning the Neptune and Dornoch surgical waste system. The following concerns were identified during the observation: a. The CNA did not wear personal protective equipment (PPE protects clothing and skin from splashes of bioburden which could later be transferred to other areas). b. The hoses for the surgical waste was connected to and draining into the hopper. Throughout the draining, a reddish/brown back flow was observed returning from the hopper drain. An odor was also noted. c. Sani-wipes were used to clean the exterior of the Neptune.			

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	Review of hospital policy, titled "Sterile Processing: Principles of Cleaning & Decontamination," revised 1/2013, states "5. Staff Safety and Personal Attire, c. Personal Protective Equipment (PPE) is required in the decontamination areas because PPE protects protect (sic) employees from splashes and other means of contamination." Review of hospital policy, titled "Sterile Processing: Principles of Cleaning & Decontamination," revised 1/2013, states "3. Environmental Design and Controls, a. ...Spills and splashes are a common occurrence in the decontamination area and this can create a need for frequent cleaning/disinfection. Floor drains should be positioned and designed to provide adequate drainage." Review of hospital policy, titled "Sterile Processing: Principles of Cleaning & Decontamination," revised 1/2013, states "6. Cleaning Agents, a. Written cleaning recommendations of the original equipment manufacturer (OEM) must be consulted. Improper usage and/or use of the wrong cleaning agent can damage and/or compromise the operation of a medical device or even harm the patient on which the device is used." During immediate interviews during the observations on 3/14/17, the CNA, indicated that she sometimes used a bleach cloth in the OR after the procedure but the hospital standard was to use the Sani-wipes, "that's what staff use." The ADON stated she assumed staff used a bleach product to clean the Neptune and Dornoch waste system.			

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	During a review of the Dornoch manual, provided by the ICP on 3/15/17 at 2:30 PM, it was noted the manufacture stipulated, "...use only bleach wipes when wiping down the carts..." During a review of the Neptune manual, the manufacture cleaning instructions stipulated the following: "Cleaning, WARNING: ALWAYS clean the equipment as indicated upon initial receipt and before each use. Failure to comply may cause infection and result in patient or healthcare staff injury..." minimum PPE "gown, gloves, face/eye shield...the following disinfectants have been validated for use with the Stryker Neptune 2 Waste Management System...Clorox Clean Up Disinfectant Cleaner with Bleach (EPA Reg. #67619-1) and CaviCide (EPA Reg. #4678-6)." Neither were used by the hospital. The Neptune manual also stipulated, "drainage requirements: Floor drain or permanent service connection per local plumbing codes..." The ICP indicated the facility would remove the hose from the hopper drainage and relocate the docking station to a floor drain as instructed by the manufacture. 4. During three separate observations of the decontamination room, on 3/13/17 at 11:30 AM, on 3/14/17 at 10 AM, and on 3/15/17 at 12:50 PM, the following concerns were identified: a. Piles of soiled surgical instruments and flexible scopes, some with dried red matter were on top of a worktable.			

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	b. The decontamination sink had soiled instruments. c. In the sink was red chunk matter. d. The sink also contained red and white dried matter. During an interview on 3/15/17 at 12:50 p.m., the APOS stated there is no designated staff assigned to the decontamination room and depending on the staffing, at times the instruments can sit on the table until day-shift staff arrives in the morning. The red matter and chunks were blood and bone fragments from an earlier case. He also indicated that the hospital staff are not consistent with pre-cleaning instruments after they are used in the OR. During an interview with the ADON of PeriOp Services, on 3/16/17 at 11:40 AM, she stated they had a staffing problem and sometimes the surgical instruments will remain on the worktable from 11:30 p.m. until day shift staff arrives. In addition, ADON stated there is no staff working in sterile processing or decontamination from 11:30 p.m. until day shift arrives in the morning. During a review of a hospital policy, titled, "Sterile Processing: Processing of Instrument & Procedure trays, revised on 1/2013, "1. All objects to be sterilized must first be thoroughly cleaned to remove all organic matter (blood and tissue) and other residue. 2. Soiled objects will be sprayed with an enzymatic agent after use, covered, and transported to the Sterile Processing Department ..." 5. During 2 separate observations (3/14/17 at 10			

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	a.m. and on 3/14/17 at 12:45 p.m.) of a Surgical Technician Lead (STL) cleaning and disinfecting soiled surgical instruments the following concerns were identified: a. During the cleaning and disinfecting of the instruments, STL obtained clean supplies from a clean storage cabinet while wearing the same gloves he used to clean soiled instruments. b. STL did not clean and disinfect the surgical processing trays. c. STL proceeded to place surgical instruments which were cleaned and disinfected, into a bloody processing tray and then placed them in to a rinse cycle. d. STL used a Sani-wipe, which was used to clean a surgical scope's camera (Stryker Lens) to also clean surgical instruments. e. STL placed the Stryker lens scope on the floor to wipe it after he cleaned and disinfected it. f. STL used surgical equipment brushes, which were stored adjacent to a used hopper cleaning brush, and cleaned surgical equipment. G. STL did not immerse all instruments in cleaning detergent. H. After cleaning a set of instruments the STL poured the water on top of a different set of surgical instruments in the adjacent sink. I. The sink was not cleaned after he completed cleaning and disinfecting the instruments. During an interview on 3/14/17 at 12:45 p.m., STL stated that he did not have to immerse the instruments as long as he was able to flush all the channels of the instruments. He also stated he reused the wipe because he was not finished			

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	cleaning all the instruments and he placed the camera on the floor so he can re-wipe it before turning it into sterile processing. During an interview with the ICP and the APOS, who were present during the observations, the APOS stated that STL's technique for cleaning the instruments was not the practice of the hospital and he did everything incorrect from start to finish. APOS acknowledged and stated that STL cross-contaminated (transfer of micro-organisms or bacteria from one area to another which can result in spread of infective material) during his technique and should not have used the soiled gloves to obtain clean supplies. The ICP stated that he would ensure the surgical instruments would get reprocessed and the processing trays should have been cleaned and disinfected. ICP stated that he would ensure STL was retrained. In addition, the ICP and the APOS stated the processing trays should have been cleaned and disinfected prior to reusing them. Review of hospital policy, titled "Sterile Processing: Processing of Instrument & Procedure Trays, revised 1/2013, states "Procedure. 3. An appropriately attired technician will place the soiled instruments into a sink filled with warm water and a hospital approved detergent. A bristled brush will be used to clean all exposed parts of the instruments. The instruments and brush will remain under water during the manual cleaning process to prevent aerosolization of contaminated water. ...5. Following cleaning, rinse with warm tap water. 6. Place into			

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	the automated washer-decontaminator. 7. Dry instruments prior to packaging....10. Use a mesh-bottomed or perforated tray or equivalent. Instrument trays will be designed for effective sterilization, drying, and orderly arrangement of instruments." Review of hospital policy, titled "Sterile Processing: Decontamination, Receiving & Handling" revised 2013, states "Policy 1.i Thoroughly clean all surfaces of equipment with hospital-approved disinfectant. Let air dry and return to appropriate clean area." 6. On 3/13/2017 at 10 a.m., during interviews while on a tour of the Perioperative Services Department and accompanied by APOS, ADON, RM 1, and SPT 1 the following observations were made: a. The document titled "Filter Change Log: Medivators DSD Edge," posted inside the Medivator door, showed that the filter was last changed on 7/15. On 3/14/17 at 11 a.m., during record review and concurrent interviews, Biomedical Engineer Manager (BEM), with a contract to manage the biomed equipment, stated he was responsible for performing Medivator Planned Maintenance (PM). BEM stated he did not know who was responsible for changing the charcoal filter every 6 months. BEM added the employee who was responsible for changing the filter no longer worked at the facility. BEM could not locate the filter change log to know the last time the filter was changed.			

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	050320	A. BUILDING _____ B. WING _____	03/16/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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	On 3/14/17 at 11:20 a.m., a telephone conference interview was conducted with the Medivator Company Representative (MR), BEM, Risk Management Staff (RM) 4, and RM 1. The Medivator Company Representative confirmed the Medivator contractor, BEM, was responsible for performing the planned maintenance and for changing the Medivator charcoal filter when due. On 3/15/17 at 10 a.m., during an observation of the Medivator reprocessor, with concurrent interview, BEM showed where the filter system and log were located posted inside the Medivator door. BEM stated the log showed the charcoal filter was changed 7/15, (greater than one month overdue according to the manufacturer's instructions.) b. On 3/13/2017 at 10 a.m. during an observation with interview, APOS held up a syringe that was lying on top of the Medivator log book and stated, "I wonder why this syringe is here?..." SPT 1 stated that the 30 cc plastic syringe, which had the tip end cut off, was being used as a replacement part for a missing "tip holder" (also called a scope cylinder). SPT 1 stated the tip holder held down the tip of the endoscope while it was being reprocessed inside of the Medivator. SPT 1 stated the tip holder was missing for at least a week and she didn't know when it would be replaced. APOS stated using this syringe for endoscope reprocessing was not appropriate or in accordance with the manufacturer's instructions for use. On 3/14/17 at 11:33 a.m., STL stated he did not			

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	know if the substitution of a plastic syringe in place of a missing scope cylinder part was compatible with paracetic acid or other Medivator reprocessing chemical products. STL added he did not know if the use of a plastic syringe with paracetic acid could result in residue being deposited onto the endoscope or the Medivator equipment itself. STL then reported he removed the plastic syringe and will wait for a replacement part. Review of hospital policy, titled "Sterile Processing: Decontamination, Receiving & Handling", revised 2013, states "Policy 1.e Inspect returned supplies to determine if all parts have been returned. Notify manager of any missing parts or instruments. 1. f Do not use any items that are not in good condition or in working order. Place any item that is not in good condition on the repair shelf." 7. On 3/13/2017 at 10 a.m. during an observation with the APOS, ADON, RM 1, and SPT 1 of the Perioperative Services Department and concurrent interview there was no method for tracking endoscope use to surgical patients and therefore no method for detecting clusters of infections or pseudo-infections associated with endoscopic procedures (e.g. surveillance system). SPT 1 stated that the Medivator was used to reprocess ureteroscopes and cystoscopes (types of endoscopes) after patient use in operating room procedure(s) once cleaning and decontamination had been completed. SPT 1 stated that the Medivator printed out a "receipt" (also called an event ticket) which showed the scope serial number, the user (staff) number and other processing values			

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	such as dates, times, stage of activity, and temperature ranges. SPT 1 confirmed that the receipt did not contain any patient identifiers for tracking the scope to patient, procedure, or location, and added that usually staff referred to the surgical schedule to determine if a scope was used for a patient. ADON confirmed that there was no method or evidence of documentation of the patient upon whom the endoscope was used, the date and time of use, the room location of use, and the type of procedure involved. On 3/14/17 at 11:33 a.m., during an interview conducted with STL, Charge Nurse of Operating Room (RN 15), ADON, and RM, STL stated that the Medivator had the capacity to track patient use to the exact scope by serial number and added "I didn't know that we should be doing this..." RN 15 stated that there was no facility process for documenting endoscope serial numbers, patient identifiers, procedure or location of use in the patient's record or in other specified manner. RN 15 said endoscopes should be tracked to ensure staff had the ability to match patient and scope if the patient developed an infection. ADON and RM 1 agreed with RN 15's statement. On 3/15/17 at 1:15 p.m. the Infection Preventionist confirmed that the facility's Quality Assurance and Safety Program, and Infection Control Surveillance System, did not have a surveillance method in place for endoscope use in the Perioperative Services Department. Review of hospital policy, titled "Sterile Processing:			

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	Principles of Cleaning & Decontamination," revised 1/2013, states "2. Cleaning, a. Manufacturers of reusable medical devices provide instructions about how to reprocess their devices between patient uses. b. Disease transmission between patients or from environmental sources to a patient can be caused by improperly processed medical devices." (According to a "Safety Communication from the FDA [Food and Drug Administration], CDC [Centers for Disease Control], and the VA [Veteran's Administration] issued on 11/19/2009" to all hospitals "... Records of the use of each endoscope, including model, serial number, and unique hospital identifier or standardized unique device identifier. Records should document the patient upon whom the endoscope was used, the date and time of use, the room location of use, and the type of procedure involved..." The program should include "...A method for detecting clusters of infections or pseudo-infections associated with endoscopic procedures (e.g., a surveillance system"). 1			

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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 1280.3(g).			

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1411 East 31st Street, Oakland, CA 94602
FACILITY ID: 140000034
PENALTY NUMBER: 020013531

Date of Survey 03/13-16/2017

This Plan of Correction is prepared and submitted as required by law. By submitting this Plan of Correction, Alameda Health System does not admit that the deficiency listed on this form exist, nor does the medical center admit to any statements, findings, facts, or conclusions that form the basis for the alleged deficiency. Alameda Health System reserves the right to challenge in legal and/or regulatory or administrative proceedings the deficiency, statements, facts, and conclusions that form the basis for the deficiency.

Tag	Corrective Action	Monitoring	Responsible Person	Completion Date
T22 DIV5 CH1 ART3-70739(a) §70739. Infection Control Program	Immediate corrective actions were implemented. Continued standardization with ongoing monitoring based on guidelines from the American Association of Medical Instrumentation (AAMI) and Association of Operating Room Nursing (AORN).			
1. The decontamination room (the process of cleansing an object or substance to remove contaminants such as micro-organisms or hazardous materials, including chemicals, radioactive substances, and infectious diseases) was not climate controlled.	Temperature and humidity gauges were ordered and installed in the decontamination room. Temperature and humidity is being monitored and recorded daily in the decontamination room per Policy and Procedure, based on AAMI guidelines. Temperature and humidity log is checked weekly by manager of sterile processing. Temperature and humidity log is checked for completeness and accuracy during leadership and Infection Control rounds. Follow-up corrective action is taken as needed	Compliance will be monitored through quarterly reporting to the Infection Control Committee from Sterile Processing of any out of range issues.	Assistant Director of Nursing for Preoperative Services (ADON) Manager of Sterile Processing	April 2017 Ongoing

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FACILITY ID: 140000034
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2. No evidence was provided to demonstrate the hospital's decontamination and sterile processing rooms were routinely and terminally cleaned (a cleaning method used in healthcare environments to control the spread of infections) or organized in a manner, which prevented the potential for cross contamination.	Review of the Policy and Procedure, no changes were made. The decontamination and sterile processing rooms and equipment were immediately terminally cleaned. A system process was implemented, using infection prevention guidelines, to separate dirty and clean supplies to prevent cross contamination. An organized daily schedule was set with Environmental Services (EVS) for terminal cleaning of the decontamination area, in a manner that will prevent the potential for cross contamination. Checklist developed to be used by EVS.	Compliance with decontamination room cleaning will be monitored by the EVS supervisors and Manager of Sterile Processing for completion. Compliance with decontamination room cleaning will be reported to the Infection Control Committee quarterly by Sterile Processing	EVS Manager and Manager of Sterile Processing	March 17, 2017 And Ongoing

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PENALTY NUMBER: 020013531

Date of Survey 03/13-16/2017

3. Several reusable patient equipment systems (Neptune 2 Rover and a Dornoch reusable suction system used during surgical procedures, to collect surgical waste) were not cleaned according to manufacture instructions and the waste was not disposed according to manufacture instructions.	Current Manufacturer's Instructions for Use (IFU) for the reusable patient suction systems was obtained and a standardized process following IFUs was implemented for waste disposal and cleaning of the reusable equipment. Staff were in-serviced on the proper disposal of waste and cleaning of the reusable patient suction systems	Initial competencies completed and reported to the Infection Control Committee. Continuous monitoring performed by the Manager of Sterile Processing.	Manager of Sterile Processing	April 2017

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PENALTY NUMBER: 020013531

Date of Survey 03/13-16/2017

4. Soiled surgical instruments were not pre-cleaned according to infection control standards and hospital policy after being used during surgical procedures and were not cleaned and disinfected according to infection control standards.	Policy and procedures were reviewed and revised. A certified sterile processing Manager ~~supervisor~~ was hired. Staff was in-serviced and competencies were developed based on guidelines from AAMI on use of personal protective equipment (PPE), pre-cleaning, cleaning, decontamination, disinfection and sterilization of reusable surgical instruments. Dedicated staff has been assigned to the decontamination room. Sterile Processing area has been incorporated in Environment of Care and Infection Prevention rounds, conducted quarterly and as needed.	Reports of staff competency completion is monitored by the Manager of Sterile Processing. Initial and ongoing staff competency is monitored by the Manager of Sterile Processing	Manager of Sterile Processing	April 2017 And ongoing

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FACILITY ID: 140000034
PENALTY NUMBER: 020013531

Date of Survey 03/13-16/2017

5. During two separate observations, while staff cleaned and disinfected soiled instruments, various concerns were identified while the staff cleaned instruments and scopes. In addition, sterilization containers (closed containers used to hold medical instruments during sterilization and preserve their sterile state until they are removed for use) were not cleaned in between use.	Policy and Procedures were reviewed and updated to reflect current guidelines by AAMI. Staff was in-serviced and competencies were developed based on guidelines from AAMI on use of personal protective equipment (PPE), pre-cleaning, cleaning, decontamination, disinfection and sterilization of reusable surgical instruments. A standardized system to decontaminate and clean sterilization containers was implemented.	Reports of staff competency completion will be provided to the Infection Control Committee. The manager of sterile processing will monitor staff competencies and compliance.	Manager of Sterile Processing	March 14, 2017

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FACILITY ID: 140000034
PENALTY NUMBER: 020013531

Date of Survey 03/13-16/2017

6. the procedures for cleaning, disinfection, and sterilization of endoscopes (a camera on a flexible tube used to look inside the body through a surgically created, or naturally occurring body opening.), and maintenance of the endoscope cleaning equipment (Medivator) were not standardized and did not follow infection control standards.	The Medivator filter was changed immediately. Routine changing of the filter was added to the preventive Medivator's maintenance log. The Medivator received required maintenance and a routine preventive maintenance schedule has been developed. Policy and Procedure for High-level disinfection was reviewed and updated with current AORN guidelines. A certified manager of sterile processing was hired. A standardized process for reprocessing flexible gastrointestinal endoscopes and other flexible endoscopes, to include pre-cleaning, cleaning, and high-level disinfection, based on AORN guidelines and manufacture's IFU, was implemented. Staff was in-serviced and competencies were developed based on guidelines from AORN on use of personal protective equipment (PPE), and infection prevention in reprocessing of flexible endoscopes. Periodic monitoring was incorporated into Leadership and Infection Prevention rounds to ensure compliance.	Staff competency completion is monitored by the managers of the respective areas, where the use of the endoscopes is being used. Notification of non-compliance and/or issues are immediately provided to the Infection preventionist for follow-up actions. PM reports will be provided to the Environment of Care Committee through Biomedical Engineering at least annually, and as needed	Manager of Sterile Processing Manager of GI Infection Preventionist	March 15, 2017 April 2017 And ongoing

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Highland Hospital, Part of Alameda Health System
1411 East 31st Street, Oakland, CA 94602
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Date of Survey 03/13-16/2017

7. there was no comprehensive Quality Assurance and Safety Program for all aspects of endoscopy procedures. (Endoscopy is the process of looking inside the body with an endoscope.)	Policy and procedures were reviewed and updated to comply with guidelines from AORN. A tracking method was developed to track individual endoscopes from point-of-use through the entire reprocessing process. A comprehensive quality assurance and safety program for all aspects of endoscopy procedures were implemented, to include: A process for verification and inspection of flexible endoscopes for cleanliness and physical damage. A system to track each scope from patient (point-of-use) through the reprocessing process. A system to record flexible endoscope procedures that identify patient, and endoscope and accessories used during the procedure.	Compliance with the use of the tracking system will be monitored by the supervisor/manager of each area where endoscopes are used. Review and evaluate flexible endoscope processing to verify compliance and identify the need for improvement.	Assistant Director of Nursing for Preoperative Services (ADON)	April 2017

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Within the meaning of Health and Safety Code §1280.3 (g), this failure constituted an immediate jeopardy (IJ), because of the potential for cross contamination and spread of bacteria and other microorganisms which could result in surgical patients contracting serious infectious diseases. Therefore, the above violations caused or were likely to cause, serious injury or death to patients who had surgical procedures.	The above violations were corrected during and immediately after the survey, as noted above. A multidisciplinary process improvement task force was formed to address these findings and to establish a standard process system-wide. Policies and Procedures for High-level disinfection and sterilization were reviewed and revised to reflect, appropriate manufacture's IFUs, and recognized best-practice infection control guidelines, to prevent cross contamination and/or spread of bacteria and other microorganisms, and to ensure patient safety. The Infection Control Program was augmented to include additional infection preventionist and expanded oversight of disinfection and sterilization. Surveillance, and infection prevention rounding has increased, to include all area performing high-level disinfection and sterilization.	Periodic Infection Prevention rounds, Environment of care rounds, and leadership rounds.	Director of Infection Prevention and Infection Preventionist	

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