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SONOMA WEST MEDICAL CENTER	501 PETALUMA AVENUE SEBASTOPOL, CA 95472

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{A 000}	INITIAL COMMENTS The following reflects the findings of the California Department of Public Health during a REVISIT SURVEY from 9/6/17 to 9/14/17. Representing the California Department of Public Health: Health Facilities Evaluator Nurses #28786 and 32961. There was one IMMEDIATE JEOPARDY called under Condition Level A700 Physical Environment as follows: On 9/6/17 at 5:50 p.m., the Chief Nursing Officer, the interim Director of Quality, the Director of Nursing, the Director of Peri-Operative Services and the Infection Control Nurse were notified that an Immediate Jeopardy was called related to the processing of endoscopes. The Immediate Jeopardy was removed on 9/13/17 at 2:48 p.m. The facility was NOT in compliance with tags A73, A77, A700 and A701 of the Plan of Correction. Entity Reported Incident #CA00549194 was investigated during the survey. No deficiencies were issued. The licensed bed capacity was 37. The census on the day of entry was 8.	{A 000}		
{A 043}	482.12 GOVERNING BODY There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized	{A 043}		

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

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{A 043}	Continued From page 1 governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ... This CONDITION is not met as evidenced by: Based on observations; staff interviews; review of administrative records; policies, procedures and document review, the Governing Body failed to ensure: 1. The hospital had an annual operating budget projected beyond 6/2017 (Refer to A073 and A077); 2. The hospital had an onsite financial Controller (Refer to A073); 3. The hospital had a functioning Quality Assurance and Performance Improvement (QAPI) program (Refer to A0263); 4. Infection Control practices were monitored and instituted (Refer to A749) [Immediate Jeopardy was called]; and 5. Equipment was maintained according to manufacturer's specifications (Refer to A701). The cumulative effects of these systemic problems resulted in the hospital's Governing Body and administrative officials inability to ensure the provision of quality health care and services in a safe environment.	{A 043}		
{A 073}	482.12(d) INSTITUTIONAL PLAN AND BUDGET The institution must have an overall institutional plan that meets the following conditions: (1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles. (2) The budget must include all anticipated	{A 073}		

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{A 073}	Continued From page 2	{A 073}		

income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.
(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.
(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:
(i) Acquisition of land;
(ii) Improvement of land, buildings, and equipment; or
(iii) The replacement, modernization, and expansion of buildings and equipment.

This STANDARD is not met as evidenced by:
Based on staff interviews and document review, the facility failed to: 1. have an annual operating budget projected beyond 6/2017, and 2. have an onsite financial controller. These failures had the potential for the Governing body, the Administrative Staff, and the Medical Staff to be unaware of critical changes with the Hospital's finances.

Findings:

1. During an interview on 9/6/17 at 11 a.m., the Chief Nursing Officer was asked to provide the hospital's operating budget. She stated she did not have it, but that it would be available by the end of the day.

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{A 073}	Continued From page 3 As of 1:15 p.m. on 9/14/17, no budget was provided by hospital staff. 2. During an interview on 9/6/17 at 11:10 a.m., the Chief Nursing Officer stated the hospital was in the process of hiring an onsite Controller. Review of the hospital's Organizational Chart, dated 9/1/17, indicated the position of Controller was "pending."	{A 073}		
{A 077}	482.12(d)(7) INSTITUTIONAL PLAN AND BUDGET The plan must be prepared- o Under the direction of the governing body; and o By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution. This STANDARD is not met as evidenced by: Based on staff interview, the facility failed to have an annual operating budget projected beyond 6/2017. This failure made it impossible for the Governing Body to approve the budget as stated in the hospital's original Plan of Correction. This had the potential for the Governing body, the Administrative Staff, and the Medical Staff to be unaware of critical changes with the Hospital's finances. Findings: Review of minutes from the August 28, 2017 Governing Body Meeting, indicated the Chief Financial Officer: "...should have financial reports prepared on a regular basis, and distributed as soon as they are available."	{A 077}		

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{A 077}	Continued From page 4 During an interview on 9/6/17 at 11 a.m., the Chief Nursing Officer was asked to provide the hospital's operating budget. She stated she did not have it, but that it would be available by the end of the day. As of 1:15 p.m. on 9/14/17, no budget was provided by hospital staff.	{A 077}		
{A 263}	482.21 QAPI The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS. This CONDITION is not met as evidenced by: Based on observations; staff interviews; policy, procedures, and document review, the hospital failed to have a functioning Quality Assurance and Performance Improvement (QAPI) program when: 1. Equipment was not maintained according to manufacturer's specifications (Refer to A701);	{A 263}		

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{A 263}	Continued From page 5 and 2. Infection Control practices were not monitored and instituted (Refer to A749 and A756). The cumulative effects of these failures resulted in the hospital's Governing Body, administrative officials and the medical staff's inability to ensure the provision of quality health care and services in a safe environment.	{A 263}		
{A 700}	482.41 PHYSICAL ENVIRONMENT The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed to maintain an environment that ensure the safety of patients when: 1. The facility did not properly evaluate the endoscope reprocessing setup and did not notify the Department prior to performing endoscope reprocessing for endoscopic procedures in their re-created setup in a dirty room (a room for cleaning the contaminated endoscopes) and the PACU (post-anesthesia care unit); (Refer to A 701) 2. The facility did not follow the national standards for the endoscope reprocessing setup; (Refer to A 701) 3. The facility did not develop an alternate policy and procedure specific to the re-created	{A 700}		

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{A 700}	Continued From page 6 endoscope reprocessing setup; (Refer to A 701) Due to the facility's failure to ensure the endoscope reprocessing setups and procedures being properly evaluated or followed the national standards for endoscope reprocessing physical setup, the Chief Nursing Officer, the interim Director of Quality, the Director of Nursing, the Director of Peri-Operative Services and the Infection Control Nurse were verbally notified an Immediate Jeopardy situation on 9/6/17 at 5:50 p.m. Removal of the Immediate Jeopardy occurred via phone with the Chief Nursing Officer on 9/13/17 at 2:48 p.m. (Refer to A 701) 4. Staff did not follow the facility's policy and procedure or manufacturer's guidelines for endoscope reprocessing; and (Refer to A 701) 5. The facility did not ensure staff followed the manufacturer's instructions for ice machine maintenance. (Refer to A 701) The cumulative effects of these systemic problems resulted in the facility's inability to provide quality of care in a safe environment.	{A 700}		
{A 701}	482.41(a) MAINTENANCE OF PHYSICAL PLANT The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility:	{A 701}		

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{A 701}	Continued From page 7	{A 701}		

1. Failed to ensure safe endoscope reprocessing setup and procedures when a) the facility did not properly evaluate the endoscope reprocessing setup and did not notify the Department prior to performing endoscope reprocessing for endoscopic procedures in their re-created setup in a dirty room (a room for cleaning the contaminated endoscopes) and the PACU (post-anesthesia care unit); b) the facility did not follow the national standards for endoscope reprocessing setup; c) the facility did not develop an alternate policy and procedure specific to the re-created endoscope reprocessing setup; d) staff did not follow the facility's policy and procedures or manufacturer's guidelines for endoscope reprocessing. The facility had performed 20 endoscopes reprocessing for endoscopic procedures for 15 patients from 8/14/17 to 9/6/17. This failure resulted in the potential to compromise infection control practices during endoscope reprocessing procedures with the potential for unsafe endoscopic procedures, which could have caused infection or harm to the patients who received the procedures or services in the facility.

Endoscope reprocessing includes cleaning and high level disinfection of the used endoscopes (the specialized instruments used by the doctors for viewing and operating the internal organs and vessels).

An endoscopic procedures allows the doctor uses specialized instruments (endoscopes) to view and operate on the internal organs and vessels.

Due to the facility's failure to ensure the endoscope reprocessing setup and procedures being properly evaluated or followed the national

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standards for endoscope reprocessing physical setup, the Chief Nursing Officer, the interim Director of Quality, the Director of Nursing, the Director of Peri-Operative Services and the Infection Control Nurse were verbally notified an Immediate Jeopardy situation on 9/6/17 at 5:50 p.m.

On 9/11/17 at 3:12 p.m., the facility presented an amended corrective plan of action including but not limited to: 1) Cancel all endoscopic procedures; 2) Identify all patients who had endoscopic procedures in the facility and notify all these patients of their potential being exposed to blood-borne pathogens with offer for tests, via certified mails; 3) Existing Scope (dirty) Room will be disassembled and returned to its original use function; and 4) All processing equipment and supplies will be removed from the PACU area and the PACU will be terminally cleaned.

Removal of the Immediate Jeopardy occurred via phone with the Chief Nursing Officer on 9/13/17 at 2:48 p.m. after observations and record reviews confirmed the existing dirty room and PACU were disassembled from endoscope reprocess setups and terminally cleaned and the patients were notified by certified mails.

2. Failed to ensure staff followed the manufacturer's instructions for ice machine maintenance. This failure had the potential for equipment necessary for patient care to be unsafe for use.

Findings:

1a)-1b) Stachybotrys (black mold) was identified in the areas of the SPD (sterile processing

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department) during the complaint validation survey ended on 6/13/17. The facility's plan of correction included "...on 5/31/2017 the [facility name] CEO (chief executive officer) suspended all clinical activities of surgery, endoscopy and reprocessing in the facility. Plans were made for the Emergency Department to redirect patients for surgical needs."

During a concurrent observation and interview on 9/6/17, at 9:10 a.m., with the Engineer and the Director of Peri-Operative Services in the SPD, the SPD including gowning area, decontamination room and sterile processing area was taped with plastic cover or the sheetrocks were removed for reconstruction due to the black mold problem. One small room, which had a sink, a hopper, and some cleaning supplies, was located next to the construction area. The Engineer stated the small room was in use for cleaning the scopes.

During a concurrent interview with the Director of Peri-Operative Services and the OR Manager on 9/6/17, at 1:30 p.m., the Director of Peri-Operative Services stated the facility had performed endoscopic procedures for five patients last week. The Director of Peri-Operative Services stated they had scheduled endoscopic procedures for 12 patients for next week. The OR Manager stated when a surgeon concerned and liked to do endoscopy for the patients in the facility, the Sterile Processing Technician assessed the area and discussed with the CEO. The OR Manager stated the CEO agreed to resume the endoscopic procedures; the first endoscopic procedure was done on 8/14/17.

During a concurrent observation and interview with the Director of Peri-Operative Services and

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OR Manager on 9/6/17, at 1:45 p.m., the small room (following refers this room to a dirty room) next to the SPD had one sink, one hopper, leak test equipment on the counter near the sink, a scope buddy mounted on the wall above the sink, some clean supplies in the shelf above the sink and counter, and a Medivator (a machine for automated endoscope reprocessing). The OR Manager stated this room was originally a clean room. The OR Manager stated they turned this room from a clean room into a dirty room for cleaning the endoscopes. The OR Manager stated the sterile processing technician soaked the endoscopes in the sink, cleaned the endoscopes, performed the leak test, and used the scope buddy to clean the endoscope in this dirty room. The OR Manager stated after the technician finished cleaning the endoscopes, the technician transported the endoscopes from the dirty room to a clean room, which was an area set up in the PACU, for manual high level disinfection. Staff had to walk pass through a public hallway from the dirty room to the PACU. In the PACU, there was two containers on a counter, with one containing a chemical solution and another one containing distilled water. The Director of Peri-Operative Services stated the solution in one container was for high level disinfection of the endoscopes and the distilled water in another container was for rinsing the endoscopes after the high level disinfection.

During a subsequent observation and interview on 9/6/17, at 3:48 p.m., in the PACU, there was one chair, one prep stand containing supplies including gauzes, lubricant, airways, and four bags of sterile water right near the counter where the disinfection of the endoscopes took place. There were also other supplies and equipment

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including a Pyxis for medication and a refrigerator for medication and other equipment for the SPD. The chair, prep stand, Pyxis, refrigerator and supplies storage were not covered. The Director of Peri-Operative Services validated the observation and stated the supplies were used by the PACU and the SPD. At 3:58 p.m., in the dirty room, there was a hand sanitizer dispenser and a soap foam dispenser mounted on the wall near the sink used for soaking the contaminated endoscopes. When asked how the staff performed hand hygiene in this room, the Director of Peri-Operative Services stated he was not sure. The Director of Peri-Operative Services stated he did not know which sink for hand washing. The Director of Peri-Operative Services stated the staff could use the hand sanitizer or soap foam from the dispensers mounted on the wall. The Director of Peri-Operative Services stated they could either use or not use water for the soap foam.

During an interview on 9/6/17, at 4:30 p.m., the Infection Control Nurse stated before they moved the clean area to the PACU, they used the current dirty room for both dirty area (area for cleaning the contaminated endoscopes) and clean area (area for manual high level disinfection of the endoscopes). The Infection Control Nurse stated they only separated the dirty area from the clean area by a red line using a tape, not physically separated the two areas. The Infection Control Nurse stated she did not perform a risk assessment prior to the above setup because the facility did not involve her for the decision making process and she did not know the facility resumed endoscope reprocessing and endoscopic procedures. The Infection control Nurse stated after about a week when she knew

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the facility had resumed the endoscopes reprocessing and endoscopic procedures, she did a risk assessment approximately on 8/28/17. She stated she discussed with the Director of Peri-Operative Services, OR Manager, and the Sterile Processing Technician regarding how they could physically separate the dirty and clean areas for endoscope processing. The Infection Control Nurse stated they decided to use the dirty room only for cleaning the contaminated endoscopes and move the clean area to the PACU for manual high level disinfection. The Infection Control Nurse stated she did not document the risk assessment. When asked what was included in her risk assessment, the Infection Control Nurse stated she just assessed how to physically separate the dirty area from the clean area. When asked how the staff performed hand hygiene when the dirty room had only one sink, the Infection Control Nurse stated she (the Infection Control Nurse) did not know; she suggested to ask the Sterile Processing Technician who actually performed the endoscope reprocessing. When asked again what was included in her risk assessment, the Infection Control Nurse stated she just assessed how to separate the dirty and clean areas.

During a concurrent observation and interview on 9/6/17, at 4:45 p.m. in the dirty room, the Infection Control Nurse stated the dirty room's setup was different from what she had recommended. She stated her impression was they had "a basin or something else" for soaking the contaminated endoscopes. The Infection Control Nurse stated she did not know they soaked the endoscopes directly in the sink and there was no basin in the room. The Infection Control Nurse stated she did not know if they used the hopper, and she did not

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{A 701}	Continued From page 13	{A 701}		

know why they did not cover the hopper. The Infection Control Nurse stated the Medivator was not in the room when she did the assessment. The Infection Control Nurse stated they should not use the alcohol based sanitizer because they were working with the enteric organisms. She stated the sanitizer dispenser was empty. The Infection Control Nurse stated they should use soap and water to wash their hands. The Infection Control Nurse stated the soap foam in the dispenser mounted on the wall required water for hand washing. In the PACU, the Infection Control Nurse stated the chair and the prep stand should not be placed near the area for manual high level disinfection because the staff needed enough room to move around and also for infection control concerns. The Infection Control Nurse stated everything stored in the PACU should be covered. The Infection Control Nurse stated she did not re-visit the dirty and clean areas after she made the recommendation for setups. She stated she used the AAMI (Association for the Advancement of Medical Instrumentation) for guidelines.

During an interview on 9/6/17, at 5:55 p.m., the Chief Nursing Officer stated she was one of the decision makers for resuming endoscope reprocessing and endoscopic procedures. The Chief Nursing Officer stated they did not notify the Department prior to resuming the endoscope reprocessing and endoscopic procedures because they thought the area was clear of mold and was safe for the procedures. The Chief Nursing Officer stated she did not know about the setups for endoscopes reprocessing. She stated she relied on the SPD staff. The Chief Nursing Officer stated they did not involve the Infection Control Nurse for a risk assessment before

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{A 701}	Continued From page 14 resuming the procedures. The American National Standards, 2015 Association for the Advancement of Medical Instrumentation, under 3.2.2 physical separation, indicated "The processing area should be defined for processing only and designed to allow for the unidirectional flow of devices from the receipt of new and/or used endoscopes to storage prior to next patient use...In all cases facilities should ensure a unidirectional flow; conduct an analysis to identify risks; and minimize these risks by policies, procedures, and education and training of processing personnel. An area should be defined for disinfection/sterilization that is separate from the manual cleaning/processing area...Rationale: Physical enclosure of the decontamination area is necessary because contaminated aerosols, droplet nuclei, and dust particles can be carried from "dirty" to "clean" areas by air currents. Separating "clean" and "dirty" areas helps prevent environmental contamination..." Under 3.2.3 Traffic control, "Traffic in the processing area should be restricted to authorized personnel. Criteria for authorized entry, movement, and attire within the decontamination and clean areas should be specified in the policies and procedures of the facility..." Under 3.3 physical facilities, 3.3.1 Space requirements, "In the decontamination area, sufficient space should be allocated for manual clean-up sinks, trash bins, laundry bins, separate handwash sinks, an emergency eyewash station, storage of cleaning chemicals and cleaning implements, PPE, automated flushing systems, suction machines, compressed air, adapters, and gauges..." Under 3.32 Sinks and accessories, "At a minimum, two sinks or one sink with two separate basins should be	{A 701}		

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used. One sink or sink basin should be designated for leak testing and manual cleaning, and the other only for rinsing..." Under 3.3.9 Hand Hygiene facilities "Hand hygiene facilities (i.e. sink, soap dispenser, towel dispenser, or alcohol-based hand rub dispensers) should be conveniently located and designated to allow good hand hygiene practices. The hand hygiene sink should be separate from the sink used to clean endoscopes. Hand hygiene facilities should be located in or near all areas where endoscopes and other devices are decontaminated and in the clean area where endoscopes are high-level disinfected or sterilized. Rationale: ...Handwashing in the sinks used for endoscope cleaning could leave handwash soap and bacteria on the endoscopes or contaminate personnel's hands..."

1c. On 9/6/17, at 4:15 p.m., when asked for a policy and procedure for endoscopes reprocessing related to the current setups, the Director of Peri-Operative Services and OR Manager provided a policy and procedure "Reprocessing of Flexible Endoscopes AER/Manual HLD" with an effective date of 3/15. The policy and procedure did not contain a review or revision date on the first page. The Director of Peri-Operative Services and OR Manager stated this was the policy and procedure being used for endoscopes reprocessing.

On 9/7/17, at 4 p.m., the Interim Director of Quality stated the facility did not have a policy and procedure specific to the current setups for endoscope reprocessing.

1d. During a concurrent observation and interview on 9/7/17, at 9:50 a.m., the Sterile Processing

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Technician demonstrated the procedures for reprocessing the endoscope. The Sterile Processing Technician cleaned the endoscope in the dirty room using the sink including leak test, cleaning the outside and inside of the scope, and using the scope buddy to flush inside of the scope. The Sterile Processing Technician wore two pairs of gloves to perform the above procedures. Before the Sterile Processing Technician used the scope buddy, she removed one pair of gloves and continued procedures with the remaining pair of gloves. After she completed with the scope buddy, she removed the gloves, gown, and face shield. The Sterile Processing Technician put on a new pair of gloves. She did not perform hand hygiene between gloves changes. She carried the scope (with no cover on the scope) directly from the sink to the bin, which was set up outside the dirty room. After she put the scope into the bin, she used the hand sanitizer from the dispenser on the wall. She stated she would not use the sink in the dirty room for hand hygiene. She stated if she had to wash her hands, she would go to another room/location where a hand washing sink was available.

During the continuous observation and interview, the Sterile Processing Technician transported the cleaned endoscope to the PACU where she performed the manual high level disinfection. The Sterile Processing Technician transported the endoscope via a closed bin in a cart and walked through a public hallway. She stated it required more time and energy to do the reprocessing due to the current setups. In the PACU, the Sterile Processing Technician stated she used two and a half gallons of disinfectant solution using a container for high level disinfection of the

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endoscope. After she tested the solution for concentration, she flushed the lumens of the endoscope. The Sterile Processing Technician stated she flushed the lumens with the solution three times. When asked how she ensured the entire scope was effectively disinfected, she stated she flushed the lumens and looked for debris. She stated if debris presented, she would bring the scope back to the dirty room to clean it again. After she flushed the lumens of the endoscope, she soaked the endoscope into the solution for disinfection. A portion of the black and white lumens/tubing were not covered by the solution. When asked if this was how she did the disinfection (with a portion of the lumens/tubing not being covered by the solution), she stated this was how she was doing it. The Sterile Processing Technician covered the container and stated she would soak the scope in the solution for eight minutes. After completed the soaking time, the Sterile Processing Technician opened the cover of the container. A portion of the black and white endoscope lumens/tubing were up in air above the solution. When asked again if this was how she did the high level disinfection, she stated that was how she was doing it. When asked how she ensured the entire scope was effectively disinfected when a portion of the black and white lumens/tubing were not covered by the solution, the Sterile Processing Technician stated she needed to add more solution. The Sterile Processing Technician took the endoscope out of the solution and put it into the distilled water in a container. She flushed the scope lumens right away. The Sterile Processing Technician stated there was no set time for the endoscope in the water. She stated she flushed through the lumens and normally took two minutes. The Sterile Processing Technician stated they changed from

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using the Medivator to manual high level disinfection approximately October 2016 because the Medivator was not working and required maintenance.

During the same observation and interview on 9/7/17, started at 9:50 a.m., the Sterile Processing Technician stated she did not go to school for the endoscope processing and she was not certified for endoscope processing. She stated she received the training from her previous boss in another facility. The Sterile Processing Technician stated the facility did not have a SPD supervisor. She reported to the Director of Peri-Operative Services or OR Manager. She stated her competency was checked off by her coworker.

During an interview on 9/7/17, at 11 a.m., The Sterile Processing Technician stated she did not participate in the assessment or decision making for the endoscope processing setups for either using the one small room for both dirty and clean areas or when they moved the clean area to the PACU. She stated she did what was told to process the endoscopes. The Sterile Processing Technician stated she did not like the first setup where both dirty and clean areas in a small room and she felt like working in "a closet." She stated when she processed the endoscopes in the small room, she did the cleaning procedures in the dirty area and then turn her body around to do the manual high level disinfection. She stated there was no separation from the dirty to clean area. She stated the dirty and clean areas should be separated because of the "airborne or contamination." She stated the air in the room was not good and it was "so hot in one small room." She stated after she worked in that small

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room for about a week, they moved the clean area to the PACU. The Sterile Processing Technician stated she just came to work and knew the change of setups (moved the clean to PACU).

During the same interview on 9/7/17, at 11 a.m., reviewed the facility's policy and procedure "Reprocessing of Flexible Endoscopes AER/Manual HLD," effective dated 3/15, with the Sterile Processing Technician. She stated she did not know about immersing the endoscope into the water for one minute so she did not do it. She stated "Now I know." She stated she did not know about the air issues when flushing the lumens with the disinfection solution and that was why when "you" asked a couple times but "I" did not mention about the air because "I don't know." When asked about her carrying the endoscope from the sink to a bin outside the dirty room, she stated now she thought of it and knew that was not good because it could be contaminated with airborne organisms. The Sterile Processing Technician stated she should have covered the endoscope. When asked if any concern of dripping water to the floor, she stated she was not thinking of it. She stated no one audited her or evaluated her performance. She stated she did not received inservice of the policy and procedure. The Sterile Processing Technician stated she liked to have the evaluation and inservices so that she could learn and correct the practices. When asked about the temperature of the disinfectant solution, she stated she measured the temperature of the solution once a day, not before each immersion/disinfection of the endoscope. When asked how she knew the correct temperature of the solution when she immersed the scope, she stated it was a wide

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{A 701}	Continued From page 20 range of temperature 59 to 68.6 degree Fahrenheit. The facility's policy and procedure titled "Reprocessing of Flexible Endoscopes AER/Manual HLD," dated 3/15, under Manual High Level Disinfection, indicated "Endoscopes mush be purged with air and externally dried prior to immersion to minimize diluting the HLD a. Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant/sterilant...b. Flush disinfectant into all channels of the endoscope until it can be seen exiting the opposite end of each channel...Channels are filled with the chemical and that no air pockets remain within the channels. Note that: 1. Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical (FDA, 2009) 2. Since internal contact cannot be visually confirmed because of scope design, purging until a steady flow of solution observed is necessary...d. Soak the endoscope in the high-level disinfectant/sterilant for the time of 8 minutes at 20 degrees Celsius for the temperature required to achieve HLD...e. Purge all channels completely with air before removing the endoscope from the high-level disinfectant/sterilant. Note that purging the channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling. f. Remove device and immerse in potable water for rinse. Immerse for one minute (only one minute is required), then flush all lumens..." The high level disinfectant manufacturer's instructions, indicated "8 minute high level disinfection at [20 degree Celsius]..."	{A 701}		

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{A 701}	Continued From page 21 During a concurrent interview and record review of the policy and procedure and the manufacturer's instructions on 9/14/17, at 12:40 p.m., with the CEO and the Director of Peri-Operative Services, the Director of Peri-Operative Services stated checking the temperature of the solution for high level disinfection once a day was not sufficient to ensure the right temperature for the solution effectively disinfect the endoscopes. The Director of Peri-Operative Services stated staff should have checked the temperature of the solution each immersion of the endoscope for disinfection. The CEO stated his understanding of the language in their policy and procedure, the temperature of the solution should be at 20 degree Celsius whenever the endoscope was soaking in the solution. During a concurrent interview with the Director of Peri-Operative Services and OR Manager on 9/7/17, at 2 p.m., both Director of Peri-Operative Services and OR Manager stated they were not SPD or endoscope reprocessing certified. The OR Manager stated she oversaw the endoscope reprocessing. She stated about two years ago, she and other staff including the technicians received inservices from the endoscope manufacturer representative for leak test, scope buddy, and connecting the endoscope to the machine (Medivator) but not all the reprocessing procedures. The OR Manager stated she evaluated the endoscope reprocessing technician for connecting the endoscope to the machine. When notified them of the technician not following the policy and procedures for endoscope reprocessing and asked how they oversaw the endoscope reprocessing and if they knew the	{A 701}		

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technician not following the procedures, both the Director of Peri-Operative Services and OR Manager did not give an answer. The Director of Peri-Operative Services stated he started working in the facility on 8/28/17 and the setups for the endoscope reprocessing were already done. He stated he did not participate in the decision making but he discussed the setups with the Infection Control Nurse. The OR Manager stated the Sterile Processing Technician set up the first room with the dirty and clean areas in the same room. The OR Manager stated she did not know about this setup. When she found out this setup, she talked to the Infection Control Nurse and moved the clean area to the PACU.

The facility provided inservices attendance roster related to endoscope reprocessing, indicated the inservice was provided on 10/2015

During an interview on 9/7/17, at 2:20 p.m., the Infection Control Nurse stated her risk assessment for the endoscope reprocessing set up was not formal, just separated the dirty area and the clean area. She stated she missed the fact that the dirty room only had one sink and she did not assess how the staff washed their hands. When asked how she did the infection surveillance related to the SPD or endoscope reprocessing, the Infection Control Nurse stated she would make sure they did not have infection case by reading the doctors' notes, following up if the patients came back to the emergency department, and calling the patients for follow up. She stated she did not follow up with the 15 patients who had the endoscopic procedures on or after 8/14/17.

The American National Standards, 2015

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Association for the Advancement of Medical Instrumentation, under 4.3 Education, training, and competency verification, indicated "It is recommended that all personnel performing processing of endoscopes be certified as a condition of employment. At a minimum, personnel should complete a certification exam...Personnel involved in endoscope processing should be provided education, training, and complete competency verification activities related to their duties upon initial hire, annually; at designated intervals; or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing. Processing activities should be closely supervised until competency is verified and documented for each processing task, from cleaning through storage of the endoscope. Facility personnel providing education, training, or competency verification for processing personnel should a) complete facility-specific education and competency verification activities related to the role of sterile processing educator; b) maintain competence necessary to provide education related to sterile processing activities, including the effective use of technologies to optimize practice; c) use regulatory and evidence-based professional guidelines as the foundation for education and training activities; d) participate in ongoing activities related to education of sterile processing personnel; and e) periodically re-educate and reassess competency of processing personnel and document completion of education, training, and competency verification activities..."

2. During a concurrent observation and interview on 9/6/17, at 9:50 a.m., in the nourishment room, the Engineer demonstrated how he cleaned the

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ice machine used for patients. After the Engineer removed all the outer covers or panels of the ice machine, the Engineer stated he would put one packet of the sanitizer to two gallon of water and put the solution into the water delivery system to clean and sanitize the ice machine. The Engineer stated he only used one chemical (sanitizer) to clean the ice machine.

The [name of sanitizer] Sanitizer & Cleaner manufacturer's instructions for use did not include the use for descaling.

The ice machine manufacturer's instructions for Maintenance and Cleaning, dated October 2014, indicated "...11. Mix a solution of ice machine scale remover...and potable water per the directions supplied with the scale remover. 12. Use a clean cloth and wash all the interior surfaces of the bin and the bin cover, agitator bar, chute cover and dispense rotor with the ice machine scale remover solution. Rinse with clear water. 13. Mix a 2 gallon solution of locally approved sanitizer. A possible sanitizer solution is one packet of [name of sanitizer] and 2 gallons of warm [95 to 105 degree Fahrenheit] potable water..."

During a concurrent interview and record review on 9/6/17, at 11:45 a.m., the Engineer reviewed the ice machine manufacturer's instructions for ice machine maintenance. The Engineer state he did not know about the solution for scale removal. The Engineer stated he only used the [name of sanitizer] for both descaling and sanitizing.

The facility's policy and procedure titled "Ice Machine Cleaning," dated 8/3/17, indicated "...Cleaning any scale buildup...Sanitize using one

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{A 701}	Continued From page 25 2 ounce packet of [name of sanitizer] Sanitizer and 2 gallons of warm, potable water..." The policy and procedure did not specify a scale remover solution for use.	{A 701}		
{A 747}	482.42 INFECTION CONTROL The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed ensure a sanitary environment and an effective infection control program when: 1. The facility did not properly evaluate the endoscope reprocessing setup and did not notify the Department prior to performing endoscope reprocessing for endoscopic procedures in their re-created setup in a dirty room (a room for cleaning the contaminated endoscopes) and the PACU (post-anesthesia care unit); (Refer to A 749) 2. The facility did not follow the national standards for endoscope reprocessing setup; (Refer to A 749) 3. The facility did not develop an alternate policy and procedure specific to the re-created endoscope reprocessing setup; (Refer to A 749) 4. Staff did not follow the facility's policy and procedures or manufacturer's guidelines for	{A 747}		

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{A 747}	Continued From page 26 endoscope reprocessing; (Refer to A 749) 5. The facility infection control nurse did not incorporate an active surveillance for infection control related to the endoscope reprocessing; (Refer to A 749) 6. The facility did not follow the national standards for storage of the endoscopes; (Refer to A 749) 7. The facility did not ensure the infection control nurse performed a formal risk assessment and evaluated the endoscope reprocessing setup following the national standards prior to performing endoscope reprocessing for endoscopic procedures in their re-created setup in a dirty room (a room for cleaning the contaminated endoscopes) and the PACU (post-anesthesia care unit); (Refer to A 756) 8. The facility did not ensure the sterile processing staff was evaluated/verified competency or provided education to improve or maintain competency; and (Refer to A 756) 9. The facility did not ensure a policy and procedure for endoscope storage following national standards. (Refer to A 756) The cumulative effects of these systemic problems resulted in the facility's inability to provide quality of care in a safe and effective manner.	{A 747}		
{A 749}	482.42(a)(1) INFECTION CONTROL PROGRAM The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and	{A 749}		

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{A 749}	Continued From page 27 communicable diseases of patients and personnel. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to implement their infection control program when: 1. The facility did not properly evaluate the endoscope reprocessing setup and did not notify the Department prior to performing endoscope reprocessing for endoscopic procedures in their re-created setup in a dirty room (a room for cleaning the contaminated endoscopes) and the PACU (post-anesthesia care unit); 2. The facility did not follow the national standards for endoscope reprocessing setup; 3. The facility did not develop an alternate policy and procedure specific to the re-created endoscope reprocessing setup; 4. Staff did not follow the facility's policy and procedures or manufacturer's guidelines for endoscope reprocessing; 5. The facility infection control nurse did not incorporate an active surveillance for infection control related to the endoscope reprocessing; and 6. The facility did not follow the national standards for storage of the endoscopes. The facility had performed 20 endoscopes reprocessing for endoscopic procedures for 15 patients from 8/14/17 to 9/6/17. This failure	{A 749}		

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resulted in the potential to compromise infection control practices during endoscope reprocessing procedures with the potential for unsafe endoscopic procedures, which could have caused infection or harm to the patients who received the procedures or services in the facility.

Endoscope reprocessing includes cleaning and high level disinfection of the used endoscopes (the specialized instruments used by the doctors for viewing and operating the internal organs and vessels).

An endoscopic procedures allows the doctor uses specialized instruments (endoscopes) to view and operate on the internal organs and vessels.

Due to the facility's failure to ensure the endoscope reprocessing setup and procedures being properly evaluated or followed the national standards for endoscope reprocessing physical setup, the Chief Nursing Officer, the interim Director of Quality, the Director of Nursing, the Director of Peri-Operative Services and the Infection Control Nurse were verbally notified an Immediate Jeopardy situation on 9/6/17 at 5:50 p.m. (Refer to A 701)

Findings:

1-2. Stachybotrys (black mold) was identified in the areas of the SPD (sterile processing department) during the complaint validation survey ended on 6/13/17. The facility's plan of correction included "...on 5/31/2017 the [facility name] CEO (chief executive officer) suspended all clinical activities of surgery, endoscopy and reprocessing in the facility. Plans were made for the Emergency Department to redirect patients

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{A 749}	Continued From page 29 for surgical needs." During a concurrent observation and interview on 9/6/17, at 9:10 a.m., with the Engineer and the Director of Peri-Operative Services in the SPD, the SPD including gowning area, decontamination room and sterile processing area was taped with plastic cover or the sheetrocks were removed for reconstruction due to the black mold problem. One small room, which had a sink, a hopper, and some cleaning supplies, was located next to the construction area. The Engineer stated the small room was in use for cleaning the scopes. During a concurrent interview with the Director of Peri-Operative Services and the OR Manager on 9/6/17, at 1:30 p.m., the Director of Peri-Operative Services stated the facility had performed endoscopic procedures for five patients last week. The Director of Peri-Operative Services stated they had scheduled endoscopic procedures for 12 patients for next week. The OR Manager stated when a surgeon concerned and liked to do endoscopy for the patients in the facility, the Sterile Processing Technician assessed the area and discussed with the CEO. The OR Manager stated the CEO agreed to resume the endoscopic procedures; the first endoscopic procedure was done on 8/14/17. During a concurrent observation and interview with the Director of Peri-Operative Services and OR Manager on 9/6/17, at 1:45 p.m., the small room (following refers this room to a dirty room) next to the SPD had one sink, one hopper, leak test equipment on the counter near the sink, a scope buddy mounted on the wall above the sink, some clean supplies in the shelf above the sink and counter, and a Medivator (a machine for	{A 749}		

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automated endoscope reprocessing). The OR Manager stated this room was originally a clean room. The OR Manager stated they turned this room from a clean room into a dirty room for cleaning the endoscopes. The OR Manager stated the sterile processing technician soaked the endoscopes in the sink, cleaned the endoscopes, performed the leak test, and used the scope buddy to clean the endoscope in this dirty room. The OR Manager stated after the technician finished cleaning the endoscopes, the technician transported the endoscopes from the dirty room to a clean room, which was an area set up in the PACU, for manual high level disinfection. Staff had to walk pass through a public hallway from the dirty room to the PACU. In the PACU, there was two containers on a counter, with one containing a chemical solution and another one containing distilled water. The Director of Peri-Operative Services stated the solution in one container was for high level disinfection of the endoscopes and the distilled water in another container was for rinsing the endoscopes after the high level disinfection.

During a subsequent observation and interview on 9/6/17, at 3:48 p.m., in the PACU, there was one chair, one prep stand containing supplies including gauzes, lubricant, airways, and four bags of sterile water right near the counter where the disinfection of the endoscopes took place. There were also other supplies and equipment including a Pyxis for medication and a refrigerator for medication and other equipment for the SPD. The chair, prep stand, Pyxis, refrigerator and supplies storage were not covered. The Director of Peri-Operative Services validated the observation and stated the supplies were used by the PACU and the SPD. At 3:58 p.m., in the dirty

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room, there was a hand sanitizer dispenser and a soap foam dispenser mounted on the wall near the sink used for soaking the contaminated endoscopes. When asked how the staff performed hand hygiene in this room, the Director of Peri-Operative Services stated he was not sure. The Director of Peri-Operative Services stated he did not know which sink for hand washing. The Director of Peri-Operative Services stated the staff could use the hand sanitizer or soap foam from the dispensers mounted on the wall. The Director of Peri-Operative Services stated they could either use or not use water for the soap foam.

During an interview on 9/6/17, at 4:30 p.m., the Infection Control Nurse stated before they moved the clean area to the PACU, they used the current dirty room for both dirty area (area for cleaning the contaminated endoscopes) and clean area (area for manual high level disinfection of the endoscopes). The Infection Control Nurse stated they only separated the dirty area from the clean area by a red line using a tape, not physically separated the two areas. The Infection Control Nurse stated she did not perform a risk assessment prior to the above setup because the facility did not involve her for the decision making process and she did not know the facility resumed endoscope reprocessing and endoscopic procedures. The Infection control Nurse stated after about a week when she knew the facility had resumed the endoscopes reprocessing and endoscopic procedures, she did a risk assessment approximately on 8/28/17. She stated she discussed with the Director of Peri-Operative Services, OR Manager, and the Sterile Processing Technician regarding how they could physically separate the dirty and clean

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areas for endoscope processing. The Infection Control Nurse stated they decided to use the dirty room only for cleaning the contaminated endoscopes and move the clean area to the PACU for manual high level disinfection. The Infection Control Nurse stated she did not document the risk assessment. When asked what was included in her risk assessment, the Infection Control Nurse stated she just assessed how to physically separate the dirty area from the clean area. When asked how the staff performed hand hygiene when the dirty room had only one sink, the Infection Control Nurse stated she (the Infection Control Nurse) did not know; she suggested to ask the Sterile Processing Technician who actually performed the endoscope reprocessing. When asked again what was included in her risk assessment, the Infection Control Nurse stated she just assessed how to separate the dirty and clean areas.

During a concurrent observation and interview on 9/6/17, at 4:45 p.m. in the dirty room, the Infection Control Nurse stated the dirty room's setup was different from what she had recommended. She stated her impression was they had "a basin or something else" for soaking the contaminated endoscopes. The Infection Control Nurse stated she did not know they soaked the endoscopes directly in the sink and there was no basin in the room. The Infection Control Nurse stated she did not know if they used the hopper, and she did not know why they did not cover the hopper. The Infection Control Nurse stated the Medivator was not in the room when she did the assessment. The Infection Control Nurse stated they should not use the alcohol based sanitizer because they were working with the enteric organisms. She stated the sanitizer dispenser was empty. The

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Infection Control Nurse stated they should use soap and water to wash their hands. The Infection Control Nurse stated the soap foam in the dispenser mounted on the wall required water for hand washing. In the PACU, the Infection Control Nurse stated the chair and the prep stand should not be placed near the area for manual high level disinfection because the staff needed enough room to move around and also for infection control concerns. The Infection Control Nurse stated everything stored in the PACU should be covered. The Infection Control Nurse stated she did not re-visit the dirty and clean areas after she made the recommendation for setups. She stated she used the AAMI (Association for the Advancement of Medical Instrumentation) for guidelines.

During an interview on 9/6/17, at 5:55 p.m., the Chief Nursing Officer stated she was one of the decision makers for resuming endoscope reprocessing and endoscopic procedures. The Chief Nursing Officer stated they did not notify the Department prior to resuming the endoscope reprocessing and endoscopic procedures because they thought the area was clear of mold and was safe for the procedures. The Chief Nursing Officer stated she did not know about the setups for endoscopes reprocessing. She stated she relied on the SPD staff. The Chief Nursing Officer stated they did not involve the Infection Control Nurse for a risk assessment before resuming the procedures.

The American National Standards, 2015 Association for the Advancement of Medical Instrumentation, under 3.2.2 physical separation, indicated "The processing area should be defined for processing only and designed to allow for the

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unidirectional flow of devices from the receipt of new and/or used endoscopes to storage prior to next patient use...In all cases facilities should ensure a unidirectional flow; conduct an analysis to identify risks; and minimize these risks by policies, procedures, and education and training of processing personnel. An area should be defined for disinfection/sterilization that is separate from the manual cleaning/processing area...Rationale: Physical enclosure of the decontamination area is necessary because contaminated aerosols, droplet nuclei, and dust particles can be carried from "dirty" to "clean" areas by air currents. Separating "clean" and "dirty" areas helps prevent environmental contamination..." Under 3.2.3 Traffic control, "Traffic in the processing area should be restricted to authorized personnel. Criteria for authorized entry, movement, and attire within the decontamination and clean areas should be specified in the policies and procedures of the facility..." Under 3.3 physical facilities, 3.3.1 Space requirements, "In the decontamination area, sufficient space should be allocated for manual clean-up sinks, trash bins, laundry bins, separate handwash sinks, an emergency eyewash station, storage of cleaning chemicals and cleaning implements, PPE, automated flushing systems, suction machines, compressed air, adapters, and gauges..." Under 3.32 Sinks and accessories, "At a minimum, two sinks or one sink with two separate basins should be used. One sink or sink basin should be designated for leak testing and manual cleaning, and the other only for rinsing..." Under 3.3.9 Hand Hygiene facilities "Hand hygiene facilities (i.e. sink, soap dispenser, towel dispenser, or alcohol-based hand rub dispensers) should be conveniently located and designated to allow

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good hand hygiene practices. The hand hygiene sink should be separate from the sink used to clean endoscopes. Hand hygiene facilities should be located in or near all areas where endoscopes and other devices are decontaminated and in the clean area where endoscopes are high-level disinfected or sterilized. Rationale:
...Handwashing in the sinks used for endoscope cleaning could leave handwash soap and bacteria on the endoscopes or contaminate personnel's hands..."

3. On 9/6/17, at 4:15 p.m., when asked for a policy and procedure for endoscopes reprocessing related to the current setups, the Director of Peri-Operative Services and OR Manager provided a policy and procedure "Reprocessing of Flexible Endoscopes AER/Manual HLD" with an effective date of 3/15. The policy and procedure did not contain a review or revision date on the first page. The Director of Peri-Operative Services and OR Manager stated this was the policy and procedure being used for endoscopes reprocessing.

On 9/7/17, at 4 p.m., the Interim Director of Quality stated the facility did not have a policy and procedure specific to the current setups for endoscope reprocessing.

4. During a concurrent observation and interview on 9/7/17, at 9:50 a.m., the Sterile Processing Technician demonstrated the procedures for reprocessing the endoscope. The Sterile Processing Technician cleaned the endoscope in the dirty room using the sink including leak test, cleaning the outside and inside of the scope, and using the scope buddy to flush inside of the scope. The Sterile Processing Technician wore

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two pairs of gloves to perform the above procedures. Before the Sterile Processing Technician used the scope buddy, she removed one pair of gloves and continued procedures with the remaining pair of gloves. After she completed with the scope buddy, she removed the gloves, gown, and face shield. The Sterile Processing Technician put on a new pair of gloves. She did not perform hand hygiene between gloves changes. She carried the scope (with no cover on the scope) directly from the sink to the bin, which was set up outside the dirty room. After she put the scope into the bin, she used the hand sanitizer from the dispenser on the wall. She stated she would not use the sink in the dirty room for hand hygiene. She stated if she had to wash her hands, she would go to another room/location where a hand washing sink was available.

During the continuous observation and interview, the Sterile Processing Technician transported the cleaned endoscope to the PACU where she performed the manual high level disinfection. The Sterile Processing Technician transported the endoscope via a closed bin in a cart and walked through a public hallway. She stated it required more time and energy to do the reprocessing due to the current setups. In the PACU, the Sterile Processing Technician stated she used two and a half gallons of disinfectant solution using a container for high level disinfection of the endoscope. After she tested the solution for concentration, she flushed the lumens of the endoscope. The Sterile Processing Technician stated she flushed the lumens with the solution three times. When asked how she ensured the entire scope was effectively disinfected, she stated she flushed the lumens and looked for

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debris. She stated if debris presented, she would bring the scope back to the dirty room to clean it again. After she flushed the lumens of the endoscope, she soaked the endoscope into the solution for disinfection. A portion of the black and white lumens/tubing were not covered by the solution. When asked if this was how she did the disinfection (with a portion of the lumens/tubing not being covered by the solution), she stated this was how she was doing it. The Sterile Processing Technician covered the container and stated she would soak the scope in the solution for eight minutes. After completed the soaking time, the Sterile Processing Technician opened the cover of the container. A portion of the black and white endoscope lumens/tubing were up in air above the solution. When asked again if this was how she did the high level disinfection, she stated that was how she was doing it. When asked how she ensured the entire scope was effectively disinfected when a portion of the black and white lumens/tubing were not covered by the solution, the Sterile Processing Technician stated she needed to add more solution. The Sterile Processing Technician took the endoscope out of the solution and put it into the distilled water in a container. She flushed the scope lumens right away. The Sterile Processing Technician stated there was no set time for the endoscope in the water. She stated she flushed through the lumens and normally took two minutes. The Sterile Processing Technician stated they changed from using the Medivator to manual high level disinfection approximately October 2016 because the Medivator was not working and required maintenance.

During the same observation and interview on 9/7/17, started at 9:50 a.m., the Sterile

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Processing Technician stated she did not go to school for the endoscope processing and she was not certified for endoscope processing. She stated she received the training from her previous boss in another facility. The Sterile Processing Technician stated the facility did not have a SPD supervisor. She reported to the Director of Peri-Operative Services or OR Manager. She stated her competency was checked off by her coworker.

During an interview on 9/7/17, at 11 a.m., The Sterile Processing Technician stated she did not participate in the assessment or decision making for the endoscope processing setups for either using the one small room for both dirty and clean areas or when they moved the clean area to the PACU. She stated she did what was told to process the endoscopes. The Sterile Processing Technician stated she did not like the first setup where both dirty and clean areas in a small room and she felt like working in "a closet." She stated when she processed the endoscopes in the small room, she did the cleaning procedures in the dirty area and then turn her body around to do the manual high level disinfection. She stated there was no separation from the dirty to clean area. She stated the dirty and clean areas should be separated because of the "airborne or contamination." She stated the air in the room was not good and it was "so hot in one small room." She stated after she worked in that small room for about a week, they moved the clean area to the PACU. The Sterile Processing Technician stated she just came to work and knew the change of setups (moved the clean area to PACU).

During the same interview on 9/7/17, at 11 a.m.,

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reviewed the facility's policy and procedure "Reprocessing of Flexible Endoscopes AER/Manual HLD," effective dated 3/15, with the Sterile Processing Technician. She stated she did not know about immersing the endoscope into the water for one minute so she did not do it. She stated "Now I know." She stated she did not know about the air issues when flushing the lumens with the disinfection solution and that was why when "you" asked a couple times but "I" did not mention about the air because "I don't know." When asked about her carrying the endoscope from the sink to a bin outside the dirty room, she stated now she thought of it and knew that was not good because it could be contaminated with airborne organisms. The Sterile Processing Technician stated she should have covered the endoscope. When asked if any concern of dripping water to the floor, she stated she was not thinking of it. She stated no one audited her or evaluated her performance. She stated she did not received inservice of the policy and procedure. The Sterile Processing Technician stated she liked to have the evaluation and inservices so that she could learn and correct the practices. When asked about the temperature of the disinfectant solution, she stated she measured the temperature of the solution once a day, not before each immersion/disinfection of the endoscope. When asked how she knew the correct temperature of the solution when she immersed the scope, she stated it was a wide range of temperature 59 to 68.6 degree Fahrenheit.

The facility's policy and procedure titled "Reprocessing of Flexible Endoscopes AER/Manual HLD," dated 3/15, under Manual High Level Disinfection, indicated "Endoscopes

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{A 749}	Continued From page 40 mush be purged with air and externally dried prior to immersion to minimize diluting the HLD a. Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant/sterilant...b. Flush disinfectant into all channels of the endoscope until it can be seen exiting the opposite end of each channel...Channels are filled with the chemical and that no air pockets remain within the channels. Note that: 1. Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical (FDA, 2009) 2. Since internal contact cannot be visually confirmed because of scope design, purging until a steady flow of solution observed is necessary...d. Soak the endoscope in the high-level disinfectant/sterilant for the time of 8 minutes at 20 degrees Celsius for the temperature required to achieve HLD...e. Purge all channels completely with air before removing the endoscope from the high-level disinfectant/sterilant. Note that purging the channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling. f. Remove device and immerse in potable water for rinse. Immerse for one minute (only one minute is required), then flush all lumens..." The high level disinfectant manufacturer's instructions, indicated "8 minute high level disinfection at [20 degree Celsius]..." During a concurrent interview and record review of the policy and procedure and the manufacturer's instructions on 9/14/17, at 12:40 p.m., with the CEO and the Director of Peri-Operative Services, the Director of Peri-Operative Services stated checking the	{A 749}		

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{A 749}	Continued From page 41 temperature of the solution for high level disinfection once a day was not sufficient to ensure the right temperature for the solution effectively disinfect the endoscopes. The Director of Peri-Operative Services stated staff should have checked the temperature of the solution each immersion of the endoscope for disinfection. The CEO stated his understanding of the language in their policy and procedure, the temperature of the solution should be at 20 degree Celsius whenever the endoscope was soaking in the solution. During a concurrent interview with the Director of Peri-Operative Services and OR Manager on 9/7/17, at 2 p.m., both Director of Peri-Operative Services and OR Manager stated they were not SPD or endoscope reprocessing certified. The OR Manager stated she oversaw the endoscope reprocessing. She stated about two years ago, she and other staff including the technicians received inservices from the endoscope manufacturer representative for leak test, scope buddy, and connecting the endoscope to the machine (Medivator) but not all the reprocessing procedures. The OR Manager stated she evaluated the endoscope reprocessing technician for connecting the endoscope to the machine. When notified them of the technician not following the policy and procedures for endoscope reprocessing and asked how they oversaw the endoscope reprocessing and if they knew the technician not following the procedures, both the Director of Peri-Operative Services and OR Manager did not give an answer. The Director of Peri-Operative Services stated he started working in the facility on 8/28/17 and the setups for the endoscope reprocessing were already done. He stated he did not participate in the decision	{A 749}		

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making but he discussed the setups with the Infection Control Nurse. The OR Manager stated the Sterile Processing Technician set up the first room with the dirty and clean areas in the same room. The OR Manager stated she did not know about this setup. When she found out this setup, she talked to the Infection Control Nurse and moved the clean area to the PACU.

The facility provided inservices attendance roster related to endoscope reprocessing, indicated the inservice was provided on 10/2015

The American National Standards, 2015 Association for the Advancement of Medical Instrumentation, under 4.3 Education, training, and competency verification, indicated "It is recommended that all personnel performing processing of endoscopes be certified as a condition of employment. At a minimum, personnel should complete a certification exam...Personnel involved in endoscope processing should be provided education, training, and complete competency verification activities related to their duties upon initial hire, annually; at designated intervals; or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing. Processing activities should be closely supervised until competency is verified and documented for each processing task, from cleaning through storage of the endoscope. Facility personnel providing education, training, or competency verification for processing personnel should a) complete facility-specific education and competency verification activities related to the role of sterile processing educator; b) maintain competence necessary to provide education related to sterile

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processing activities, including the effective use of technologies to optimize practice; c) use regulatory and evidence-based professional guidelines as the foundation for education and training activities; d) participate in ongoing activities related to education of sterile processing personnel; and e) periodically re-educate and reassess competency of processing personnel and document completion of education, training, and competency verification activities..."

5. During an interview on 9/7/17, at 2:20 p.m., the Infection Control Nurse stated her risk assessment for the endoscope reprocessing set up was not formal, just separated the dirty area and the clean area. She stated she missed the fact that the dirty room only had one sink and she did not assess how the staff washed their hands. When asked how she did the infection surveillance related to the SPD or endoscope reprocessing, the Infection Control Nurse stated she would make sure they did not have infection case by reading the doctors' notes, following up if the patients came back to the emergency department, and calling the patients for follow up. She stated she did not follow up with the 15 patients who had the endoscopic procedures on or after 8/14/17.

The facility's policy and procedure titled "Infection Prevention and Control Annual Risk Assessment and Plan," dated 3/30/17, under Scope of Services, indicated "Infection Prevention and Control is a facility-wide patient safety component involving all departments. The Infection Preventionist, along with the Pharmacy, Infection and Blood Committee, determines the specific focus of surveillance, education, and consultation efforts on and ongoing basis, dependent on

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hospital Epidemiology, community disease surveillance and real or perceived local or world threats..."

6. During a concurrent observation and interview on 9/6/17, at 1:45 p.m., in the anesthesia supply room where the endoscopes were stored, the OR Manager stated the reprocessed endoscopes were stored for 10 days. She stated if the endoscopes were not being used, the staff would reprocess the endoscopes again.

During a concurrent observation and interview on 9/7/17, started at 9:50 a.m., the Sterile Processing Technician stated after she finished processing the endoscopes, she transported the endoscopes to the endoscope storage area. She stated she hung the endoscopes to the storage and dated the endoscopes. The Sterile Processing Technician stated the endoscopes were stored for 10 days. If the endoscopes were not being used, she would reprocess the endoscopes again.

The facility's policy and procedure titled "Reprocessing of Flexible Endoscopes," reviewed 07/2017, under Reprocessing Unused Scopes, indicated "...The shelflife for an unused scopes are 7-10 days..."

During a concurrent record review and interview on 9/14/17, at 12:40 a.m., the Director of Peri-Operative Services stated the facility's policy and procedure allowed the endoscopes to be stored up to 10 days to cover the weekends. He stated the facility did not have staff to reprocess the endoscopes during the weekend, so it could have passed the 7 days. The Director of Peri-Operative Services stated they followed

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{A 749}	Continued From page 45 APIC (Association for Professionals in Infection Control and Epidemiology) for the endoscope storage. Reviewed the training documents presented by the endoscopes' manufacturer representative, provided by the facility, under Proper Storage, indicated AORN (Association of periOperative Registered Nurses) position was 5 day and APIC position was 7 days. The Director of Peri-Operative Services reviewed the endoscopes' manufacturer operational manual and stated the manual did not specify the shelflife of the endoscopes. He stated the facility followed the most stringent national standards.	{A 749}		
{A 756}	482.42(b) INFECTION CONTROL LEADERSHIP RESPONSIBILITIES Standard: Responsibilities of Chief Executive Officer, Medical Staff, and Director of Nursing Services The chief executive officer, the medical staff, and the director of nursing must-- (1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility:	{A 756}		

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{A 756}	Continued From page 46 1. Failed to ensure the infection control nurse performed a formal risk assessment and evaluated the endoscope reprocessing setup following the national standards or notified the Department prior to performing endoscope reprocessing for endoscopic procedures in their re-created setup in a dirty room (a room for cleaning the contaminated endoscopes) and the PACU (post-anesthesia care unit); and 2. Failed to ensure the sterile processing staff was evaluated/verified competency or provided education to improve or maintain competency; and The facility had performed 20 endoscopes reprocessing for endoscopic procedures for 15 patients from 8/14/17 to 9/6/17. This failure resulted in the potential to compromise infection control practices during endoscope reprocessing procedures with the potential for unsafe endoscopic procedures, which could have caused infection or harm to the patients who received the procedures or services in the facility. Endoscope reprocessing includes cleaning and high level disinfection of the used endoscopes (the specialized instruments used by the doctors for viewing and operating the internal organs and vessels). An endoscopic procedures allows the doctor uses specialized instruments (endoscopes) to view and operate on the internal organs and vessels. Findings: 1. Stachybotrys (black mold) was identified in the	{A 756}		

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{A 756}	Continued From page 47 areas of the SPD (sterile processing department) during the complaint validation survey ended on 6/13/17. The facility's plan of correction included "...on 5/31/2017 the [facility name] CEO (chief executive officer) suspended all clinical activities of surgery, endoscopy and reprocessing in the facility. Plans were made for the Emergency Department to redirect patients for surgical needs." During a concurrent observation and interview on 9/6/17, at 9:10 a.m., with the Engineer and the Director of Peri-Operative Services in the SPD, the SPD including gowning area, decontamination room and sterile processing area was taped with plastic cover or the sheetrocks were removed for reconstruction due to the black mold problem. One small room, which had a sink, a hopper, and some cleaning supplies, was located next to the construction area. The Engineer stated the small room was in use for cleaning the scopes. During a concurrent interview with the Director of Peri-Operative Services and the OR Manager on 9/6/17, at 1:30 p.m., the Director of Peri-Operative Services stated the facility had performed endoscopic procedures for five patients last week. The Director of Peri-Operative Services stated they had scheduled endoscopic procedures for 12 patients for next week. The OR Manager stated when a surgeon concerned and liked to do endoscopy for the patients in the facility, the Sterile Processing Technician assessed the area and discussed with the CEO. The OR Manager stated the CEO agreed to resume the endoscopic procedures; the first endoscopic procedure was done on 8/14/17. During a concurrent observation and interview	{A 756}		

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with the Director of Peri-Operative Services and OR Manager on 9/6/17, at 1:45 p.m., the small room (following refers this room to a dirty room) next to the SPD had one sink, one hopper, leak test equipment on the counter near the sink, a scope buddy mounted on the wall above the sink, some clean supplies in the shelf above the sink and counter, and a Medivator (a machine for automated endoscope reprocessing). The OR Manager stated this room was originally a clean room. The OR Manager stated they turned this room from a clean room into a dirty room for cleaning the endoscopes. The OR Manager stated the sterile processing technician soaked the endoscopes in the sink, cleaned the endoscopes, performed the leak test, and used the scope buddy to clean the endoscope in this dirty room. The OR Manager stated after the technician finished cleaning the endoscopes, the technician transported the endoscopes from the dirty room to a clean room, which was an area set up in the PACU, for manual high level disinfection. Staff had to walk pass through a public hallway from the dirty room to the PACU. In the PACU, there was two containers on a counter, with one containing a chemical solution and another one containing distilled water. The Director of Peri-Operative Services stated the solution in one container was for high level disinfection of the endoscopes and the distilled water in another container was for rinsing the endoscopes after the high level disinfection.

During a subsequent observation and interview on 9/6/17, at 3:48 p.m., in the PACU, there was one chair, one prep stand containing supplies including gauzes, lubricant, airways, and four bags of sterile water right near the counter where the disinfection of the endoscopes took place.

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There were also other supplies and equipment including a Pyxis for medication and a refrigerator for medication and other equipment for the SPD. The chair, prep stand, Pyxis, refrigerator and supplies storage were not covered. The Director of Peri-Operative Services validated the observation and stated the supplies were used by the PACU and the SPD. At 3:58 p.m., in the dirty room, there was a hand sanitizer dispenser and a soap foam dispenser mounted on the wall near the sink used for soaking the contaminated endoscopes. When asked how the staff performed hand hygiene in this room, the Director of Peri-Operative Services stated he was not sure. The Director of Peri-Operative Services stated he did not know which sink for hand washing. The Director of Peri-Operative Services stated the staff could use the hand sanitizer or soap foam from the dispensers mounted on the wall. The Director of Peri-Operative Services stated they could either use or not use water for the soap foam.

During an interview on 9/6/17, at 4:30 p.m., the Infection Control Nurse stated before they moved the clean area to the PACU, they used the current dirty room for both dirty area (area for cleaning the contaminated endoscopes) and clean area (area for manual high level disinfection of the endoscopes). The Infection Control Nurse stated they only separated the dirty area from the clean area by a red line using a tape, not physically separated the two areas. The Infection Control Nurse stated she did not perform a risk assessment prior to the above setup because the facility did not involve her for the decision making process and she did not know the facility resumed endoscope reprocessing and endoscopic procedures. The Infection control

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Nurse stated after about a week when she knew the facility had resumed the endoscopes reprocessing and endoscopic procedures, she did a risk assessment approximately on 8/28/17. She stated she discussed with the Director of Peri-Operative Services, OR Manager, and the Sterile Processing Technician regarding how they could physically separate the dirty and clean areas for endoscope processing. The Infection Control Nurse stated they decided to use the dirty room only for cleaning the contaminated endoscopes and move the clean area to the PACU for manual high level disinfection. The Infection Control Nurse stated she did not document the risk assessment. When asked what was included in her risk assessment, the Infection Control Nurse stated she just assessed how to physically separate the dirty area from the clean area. When asked how the staff performed hand hygiene when the dirty room had only one sink, the Infection Control Nurse stated she (the Infection Control Nurse) did not know; she suggested to ask the Sterile Processing Technician who actually performed the endoscope reprocessing. When asked again what was included in her risk assessment, the Infection Control Nurse stated she just assessed how to separate the dirty and clean areas.

During a concurrent observation and interview on 9/6/17, at 4:45 p.m. in the dirty room, the Infection Control Nurse stated the dirty room's setup was different from what she had recommended. She stated her impression was they had "a basin or something else" for soaking the contaminated endoscopes. The Infection Control Nurse stated she did not know they soaked the endoscopes directly in the sink and there was no basin in the room. The Infection Control Nurse stated she did

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not know if they used the hopper, and she did not know why they did not cover the hopper. The Infection Control Nurse stated the Medivator was not in the room when she did the assessment. The Infection Control Nurse stated they should not use the alcohol based sanitizer because they were working with the enteric organisms. She stated the sanitizer dispenser was empty. The Infection Control Nurse stated they should use soap and water to wash their hands. The Infection Control Nurse stated the soap foam in the dispenser mounted on the wall required water for hand washing. In the PACU, the Infection Control Nurse stated the chair and the prep stand should not be placed near the area for manual high level disinfection because the staff needed enough room to move around and also for infection control concerns. The Infection Control Nurse stated everything stored in the PACU should be covered. The Infection Control Nurse stated she did not re-visit the dirty and clean areas after she made the recommendation for setups. She stated she used the AAMI (Association for the Advancement of Medical Instrumentation) for guidelines.

During an interview on 9/7/17, at 2:20 p.m., the Infection Control Nurse stated her risk assessment for the endoscope reprocessing set up was not formal, just separated the dirty area and the clean area. She stated she missed the fact that the dirty room only had one sink and she did not assess how the staff washed their hands. When asked how she did the infection surveillance related to the SPD or endoscope reprocessing, the Infection Control Nurse stated she would make sure they did not have infection case by reading the doctors' notes, following up if the patients came back to the emergency

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department, and calling the patients for follow up. She stated she did not follow up with the 15 patients who had the endoscopic procedures on or after 8/14/17.

During an interview on 9/6/17, at 5:55 p.m., the Chief Nursing Officer stated she was one of the decision makers for resuming endoscope reprocessing and endoscopic procedures. The Chief Nursing Officer stated they did not notify the Department prior to resuming the endoscope reprocessing and endoscopic procedures because they thought the area was clear of mold and was safe for the procedures. The Chief Nursing Officer stated she did not know about the setups for endoscopes reprocessing. She stated she relied on the SPD staff. The Chief Nursing Officer stated they did not involve the Infection Control Nurse for a risk assessment before resuming the procedures.

The American National Standards, 2015 Association for the Advancement of Medical Instrumentation, under 3.2.2 physical separation, indicated "The processing area should be defined for processing only and designed to allow for the unidirectional flow of devices from the receipt of new and/or used endoscopes to storage prior to next patient use...In all cases facilities should ensure a unidirectional flow; conduct an analysis to identify risks; and minimize these risks by policies, procedures, and education and training of processing personnel. An area should be defined for disinfection/sterilization that is separate from the manual cleaning/processing area...Rationale: Physical enclosure of the decontamination area is necessary because contaminated aerosols, droplet nuclei, and dust particles can be carried from "dirty" to "clean"

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areas by air currents. Separating "clean" and "dirty" areas helps prevent environmental contamination..." Under 3.2.3 Traffic control, "Traffic in the processing area should be restricted to authorized personnel. Criteria for authorized entry, movement, and attire within the decontamination and clean areas should be specified in the policies and procedures of the facility..." Under 3.3 physical facilities, 3.3.1 Space requirements, "In the decontamination area, sufficient space should be allocated for manual clean-up sinks, trash bins, laundry bins, separate handwash sinks, an emergency eyewash station, storage of cleaning chemicals and cleaning implements, PPE, automated flushing systems, suction machines, compressed air, adapters, and gauges..." Under 3.32 Sinks and accessories, "At a minimum, two sinks or one sink with two separate basins should be used. One sink or sink basin should be designated for leak testing and manual cleaning, and the other only for rinsing..." Under 3.3.9 Hand Hygiene facilities "Hand hygiene facilities (i.e. sink, soap dispenser, towel dispenser, or alcohol-based hand rub dispensers) should be conveniently located and designated to allow good hand hygiene practices. The hand hygiene sink should be separate from the sink used to clean endoscopes. Hand hygiene facilities should be located in or near all areas where endoscopes and other devices are decontaminated and in the clean area where endoscopes are high-level disinfected or sterilized. Rationale:
...Handwashing in the sinks used for endoscope cleaning could leave handwash soap and bacteria on the endoscopes or contaminate personnel's hands..."

On 9/6/17, at 4:15 p.m., when asked for a policy

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and procedure for endoscopes reprocessing related to the current setups, the Director of Peri-Operative Services and OR Manager provided a policy and procedure "Reprocessing of Flexible Endoscopes AER/Manual HLD" with an effective date of 3/15. The policy and procedure did not contain a review or revision date on the first page. The Director of Peri-Operative Services and OR Manager stated this was the policy and procedure being used for endoscopes reprocessing.

On 9/7/17, at 4 p.m., the Interim Director of Quality stated the facility did not have a policy and procedure specific to the current setups for endoscope reprocessing.

2. During a concurrent observation and interview on 9/7/17, at 9:50 a.m., the Sterile Processing Technician demonstrated the procedures for reprocessing the endoscope. The Sterile Processing Technician cleaned the endoscope in the dirty room using the sink including leak test, cleaning the outside and inside of the scope, and using the scope buddy to flush inside of the scope. The Sterile Processing Technician wore two pairs of gloves to perform the above procedures. Before the Sterile Processing Technician used the scope buddy, she removed one pair of gloves and continued procedures with the remaining pair of gloves. After she completed with the scope buddy, she removed the gloves, gown, and face shield. The Sterile Processing Technician put on a new pair of gloves. She did not perform hand hygiene between gloves changes. She carried the scope (with no cover on the scope) directly from the sink to the bin, which was set up outside the dirty room. After she put the scope into the bin, she used the hand

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sanitizer from the dispenser on the wall. She stated she would not use the sink in the dirty room for hand hygiene. She stated if she had to wash her hands, she would go to another room/location where a hand washing sink was available.

During the continuous observation and interview, the Sterile Processing Technician transported the cleaned endoscope to the PACU where she performed the manual high level disinfection. The Sterile Processing Technician transported the endoscope via a closed bin in a cart and walked through a public hallway. She stated it required more time and energy to do the reprocessing due to the current setups. In the PACU, the Sterile Processing Technician stated she used two and a half gallons of disinfectant solution using a container for high level disinfection of the endoscope. After she tested the solution for concentration, she flushed the lumens of the endoscope. The Sterile Processing Technician stated she flushed the lumens with the solution three times. When asked how she ensured the entire scope was effectively disinfected, she stated she flushed the lumens and looked for debris. She stated if debris presented, she would bring the scope back to the dirty room to clean it again. After she flushed the lumens of the endoscope, she soaked the endoscope into the solution for disinfection. A portion of the black and white lumens/tubing were not covered by the solution. When asked if this was how she did the disinfection (with a portion of the lumens/tubing not being covered by the solution), she stated this was how she was doing it. The Sterile Processing Technician covered the container and stated she would soak the scope in the solution for eight minutes. After completed the soaking time, the

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{A 756}	Continued From page 56 Sterile Processing Technician opened the cover of the container. A portion of the black and white endoscope lumens/tubing were up in air above the solution. When asked again if this was how she did the high level disinfection, she stated that was how she was doing it. When asked how she ensured the entire scope was effectively disinfected when a portion of the black and white lumens/tubing were not covered by the solution, the Sterile Processing Technician stated she needed to add more solution. The Sterile Processing Technician took the endoscope out of the solution and put it into the distilled water in a container. She flushed the scope lumens right away. The Sterile Processing Technician stated there was no set time for the endoscope in the water. She stated she flushed through the lumens and normally took two minutes. The Sterile Processing Technician stated they changed from using the Medivator to manual high level disinfection approximately October 2016 because the Medivator was not working and required maintenance. During the same observation and interview on 9/7/17, started at 9:50 a.m., the Sterile Processing Technician stated she did not go to school for the endoscope processing and she was not certified for endoscope processing. She stated she received the training from her previous boss in another facility. The Sterile Processing Technician stated the facility did not have a SPD supervisor. She reported to the Director of Peri-Operative Services or OR Manager. She stated her competency was checked off by her coworker. During an interview on 9/7/17, at 11 a.m., The Sterile Processing Technician stated she did not	{A 756}		

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participate in the assessment or decision making for the endoscope processing setups for either using the one small room for both dirty and clean areas or when they moved the clean area to the PACU. She stated she did what was told to process the endoscopes. The Sterile Processing Technician stated she did not like the first setup where both dirty and clean areas in a small room and she felt like working in "a closet." She stated when she processed the endoscopes in the small room, she did the cleaning procedures in the dirty area and then turn her body around to do the manual high level disinfection. She stated there was no separation from the dirty to clean area. She stated the dirty and clean areas should be separated because of the "airborne or contamination." She stated the air in the room was not good and it was "so hot in one small room." She stated after she worked in that small room for about a week, they moved the clean area to the PACU. The Sterile Processing Technician stated she just came to work and knew the change of setups (moved the clean area to PACU).

During the same interview on 9/7/17, at 11 a.m., reviewed the facility's policy and procedure "Reprocessing of Flexible Endoscopes AER/Manual HLD," effective dated 3/15, with the Sterile Processing Technician. She stated she did not know about immersing the endoscope into the water for one minute so she did not do it. She stated "Now I know." She stated she did not know about the air issues when flushing the lumens with the disinfection solution and that was why when "you" asked a couple times but "I" did not mention about the air because "I don't know." When asked about her carrying the endoscope from the sink to a bin outside the dirty room, she

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stated now she thought of it and knew that was not good because it could be contaminated with airborne organisms. The Sterile Processing Technician stated she should have covered the endoscope. When asked if any concern of dripping water to the floor, she stated she was not thinking of it. She stated no one audited her or evaluated her performance. She stated she did not received inservice of the policy and procedure. The Sterile Processing Technician stated she liked to have the evaluation and inservices so that she could learn and correct the practices. When asked about the temperature of the disinfectant solution, she stated she measured the temperature of the solution once a day, not before each immersion/disinfection of the endoscope. When asked how she knew the correct temperature of the solution when she immersed the scope, she stated it was a wide range of temperature 59 to 68.6 degree Fahrenheit.

The facility's policy and procedure titled "Reprocessing of Flexible Endoscopes AER/Manual HLD," dated 3/15, under Manual High Level Disinfection, indicated "Endoscopes mush be purged with air and externally dried prior to immersion to minimize diluting the HLD a. Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant/sterilant...b. Flush disinfectant into all channels of the endoscope until it can be seen exiting the opposite end of each channel...Channels are filled with the chemical and that no air pockets remain within the channels. Note that: 1. Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical (FDA, 2009) 2. Since internal contact cannot be visually

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{A 756}	Continued From page 59 confirmed because of scope design, purging until a steady flow of solution observed is necessary...d. Soak the endoscope in the high-level disinfectant/sterilant for the time of 8 minutes at 20 degrees Celsius for the temperature required to achieve HLD...e. Purge all channels completely with air before removing the endoscope from the high-level disinfectant/sterilant. Note that purging the channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling. f. Remove device and immerse in potable water for rinse. Immerse for one minute (only one minute is required), then flush all lumens..." The high level disinfectant manufacturer's instructions, indicated "8 minute high level disinfection at [20 degree Celsius]..." During a concurrent interview and record review of the policy and procedure and the manufacturer's instructions on 9/14/17, at 12:40 p.m., with the CEO and the Director of Peri-Operative Services, the Director of Peri-Operative Services stated checking the temperature of the solution for high level disinfection once a day was not sufficient to ensure the right temperature for the solution effectively disinfect the endoscopes. The Director of Peri-Operative Services stated staff should have checked the temperature of the solution each immersion of the endoscope for disinfection. The CEO stated his understanding of the language in their policy and procedure, the temperature of the solution should be at 20 degree Celsius whenever the endoscope was soaking in the solution.	{A 756}		

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{A 756}	Continued From page 60 During a concurrent interview with the Director of Peri-Operative Services and OR Manager on 9/7/17, at 2 p.m., both Director of Peri-Operative Services and OR Manager stated they were not SPD or endoscope reprocessing certified. The OR Manager stated she oversaw the endoscope reprocessing. She stated about two years ago, she and other staff including the technicians received inservices from the endoscope manufacturer representative for leak test, scope buddy, and connecting the endoscope to the machine (Medivator) but not all the reprocessing procedures. The OR Manager stated she evaluated the endoscope reprocessing technician for connecting the endoscope to the machine. When notified them of the technician not following the policy and procedures for endoscope reprocessing and asked how they oversaw the endoscope reprocessing and if they knew the technician not following the procedures, both the Director of Peri-Operative Services and OR Manager did not give an answer. The facility provided inservices attendance roster related to endoscope reprocessing, indicated the inservice was provided on 10/2015 The American National Standards, 2015 Association for the Advancement of Medical Instrumentation, under 4.3 Education, training, and competency verification, indicated "It is recommended that all personnel performing processing of endoscopes be certified as a condition of employment. At a minimum, personnel should complete a certification exam...Personnel involved in endoscope processing should be provided education, training, and complete competency verification activities related to their duties upon initial hire,	{A 756}		

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{A 756}	Continued From page 61 annually; at designated intervals; or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing. Processing activities should be closely supervised until competency is verified and documented for each processing task, from cleaning through storage of the endoscope. Facility personnel providing education, training, or competency verification for processing personnel should a) complete facility-specific education and competency verification activities related to the role of sterile processing educator; b) maintain competence necessary to provide education related to sterile processing activities, including the effective use of technologies to optimize practice; c) use regulatory and evidence-based professional guidelines as the foundation for education and training activities; d) participate in ongoing activities related to education of sterile processing personnel; and e) periodically re-educate and reassess competency of processing personnel and document completion of education, training, and competency verification activities..." The facility's policy and procedure titled "Infection Prevention and Control Annual Risk Assessment and Plan," dated 3/30/17, under Scope of Services, indicated "Infection Prevention and Control is a facility-wide patient safety component involving all departments. The Infection Preventionist, along with the Pharmacy, Infection and Blood Committee, determines the specific focus of surveillance, education, and consultation efforts on and ongoing basis, dependent on hospital Epidemiology, community disease surveillance and real or perceived local or world threats..."	{A 756}		