

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001146	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/17/2016
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NAME OF PROVIDER OR SUPPLIER SURGERY CENTER OF CARMEL THE	STREET ADDRESS, CITY, STATE, ZIP CODE 12188 N MERIDIAN ST BLDG A STE 150 CARMEL, IN 46032
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Q 0000 Bldg. 00	This visit was for a re-certification survey. Facility Number: 004746 Survey Date: 2/15/2016 thru 2/17/2016 QA: cjl 03/15/16 IDR Committe held on 04-27-16. Tag Q0223 deleted. JL	Q 0000		
Q 0101 Bldg. 00	416.44(a)(1) PHYSICAL ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. Based on document review and interview, the facility failed to ensure three (3) of five (5) operating rooms met 15 air exchanges per hour. Findings included: 1. On 2/15/2016 at 10:00 AM, staff member #1 (Administrative Director) was requested to provide documentation	Q 0101	1 The Facility Administrator notified Diversified Anesthesia to better understand Air exchange reports Center has never been cited for Air Exchange issues and felt she needed clarification Per our representative from Diversified Anesthesia our air exchanges meet CMS/State requirements Please see attached forms Center did notify Freije to let them know that	04/06/2016

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>of operating room air exchanges provided to five operating rooms (OR) and only 4 of 5 operating rooms documentation was provided.</p> <p>2. Review of Room Ventilation Survey Reports indicated "operating rooms are required to provide 15 air exchanges per hour." Three of four operating room (OR 1, OR 2 and OR 3) documentation that was provided did not meet the required 15 air exchanges per hour and the facility did not provide documentation for operating room #6:</p> <p>a. OR 1 - 11.9 air exchanges per hour. b. OR 2 - 12.4 air exchanges per hour. c. OR 3 - 5.5 air exchanges per hour. d. OR 4 - 17.8 air exchanges per hour. e. OR 6 - No Ventilation Survey Report available.</p> <p>3. In interview at 1:55 PM on 2/17/2016, staff member #1 confirmed the above and no other documentation was provided by exit.</p>		<p>they did not report appropriately our ventilation for OR6 Diversified came out on 4-6-16 to do another test on the Air exchanges in OR 6(See attachment A) Per Brandon you add the two numbers together to read the air exchanges (See attachment A for the results ie OR I 11'9+45'6= 57'5 air exchange 2 Diversified stated that if there ever was an issue I would be notified immediately of any problems Administrator had Brandon in-service her on how to read the report appropriately. 3 Administrator report in infection control committee 4 04/6/2016 next inspection will be for all the OR May 6, 2016</p>		

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Q 0224 Bldg. 00	<p>416.50(c)(1)(2)(3) ADVANCED DIRECTIVES</p> <p>The ASC must comply with the following requirements:</p> <p>(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.</p> <p>(2) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.</p> <p>(3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.</p> <p>Based on document review, observation and interview, the facility failed to provide the patient or patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws.</p> <p>Findings included:</p> <p>1. Review of Patient Rights and Responsibilities policy (last approved 5/19/15) indicated the policy does not describe that patients or patient's</p>	O 0224	<p>1 Administrator Printed a copy of the Indiana State Dept of Health " Advance Directive Your right to Decide" from the website Copies of the Advance Directive will be displayed at the front desk for review Copies will also be offer to the patient at the Physician's office, front desk, and from our website Receptionist will monitor to make sure that copies are available daily with her morning duties (See Attachment F)</p> <p>2 Receptionist will monitor daily to make sure that state law copies on Advance Directives are available for patients at the front</p>	02/20/2016

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	<p>representatives should receive description of applicable State health and safety laws on advance directives.</p> <p>2. At 9:30 AM on 2/15/2016, The Surgery Center of Carmel's Patient Rights and Responsibilities brochure was observed at the reception desk for easy access by patients or patient's representatives.</p> <p>3. The Surgery Center of Carmel's Patient Rights and Responsibilities brochure instructed how to obtain additional information on the advance directives, but lacked the specific description of applicable State health and safety laws on advance directives.</p> <p>4. At 11:30 AM on 2/17/2016, staff member #2 (Receptionist) indicated the advance directives are part of the brochure. The staff member indicated the patient can access a copy of the advance directives at a web-site listed in the Patient Rights and Responsibilities brochure.</p> <p>5. At 12:15 PM on 2/17/2016, staff member #1 (Administrator Director) confirmed the patient could get a copy of description of applicable State health and safety laws through the web-site listed in the brochure, The center does not</p>		<p>desk 3.receptionist 4 2/20/2016</p>				

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Q 0229 Bldg. 00	<p>provide to the patient a copy of the applicable State health and safety laws.</p> <p>416.50(e)(1)(iii) EXERCISE OF RIGHTS - INFORMED CONSENT [[(1) The patient has the right to the following:]</p> <p>(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.</p> <p>Based on document review and interview, the informed consent documentation failed to assure that consent was obtained prior to the surgical procedure for 17 of 20 medical records (MR) reviewed (patient #s 3, 4, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19 and 20).</p> <p>Findings include:</p> <ol style="list-style-type: none"> The policy/procedure Consent Signature (approved 5-15) failed to indicate a requirement for the informed consent to be obtained prior to performing the surgical procedure. Review of the informed consent for patient #3 failed to indicate the time when signed by the patient or patient's representative. 	O 0229	<p>1 The Administrator Change the consent form so that the patient will sign date and time their signature Both witnesses with date after they witness the patient sign the form (See Attachment D/F), Policy 201 has been updated to reflect that the patient and/or responsible adult sign, date and time consent after approval of procedure has been confirmed with no questions or concerns</p> <p>2 Deficiency will be corrected due to the change in the consent form. The Med Rec consultant and peer review staff will review the consent and monitor if date and time are not marked on a monthly and quarterly inspection and report to QAPI Committee. The new form was presented to the Medical Advisory Committee and the GB for approval 3 Administrator 4 3/1/2016</p>	03/01/2016

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Q 0241 Bldg. 00	<p>3. Review of the informed consent for patient #s 4, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19 and 20 failed to indicate the date or time when signed by the patient or patient's representative.</p> <p>4. In interview on 2-17-16 at 1530 hours, staff A1 confirmed that the informed consents for patient #s 3, 4, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19 and 20 failed to indicate a date and/or time when signed to confirm the consent was obtained prior to the surgical procedure.</p> <p>416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. Based on document review, observation and interview, the center failed to ensure its restricted surgical environment and patient care areas were maintained in a sanitary manner for 3 of 6 operating rooms (ORs) and the pre and post-op areas of the center.</p> <p>Findings include:</p> <p>1. The Association of periOperative Nurses (AORN) Recommended Practices for Environmental Cleaning (2014) indicated the following: "Disinfectants</p>	Q 0241	1 2/22/16 the Administrator, Infection RN, and OR Manager met to review our policy and housekeeping protocol for the facility The Policy 121D(Attachment G) was updated and awaiting approval by MAC and Governing Board Monitoring form was re-done to review the center weekly by staff and QBM (Attachment H) OR Manager, PACU manager, and BOM will perform weekly walk thru of their areas and report findings to the Infection RN QBM and the infection RN will also do weekly walks of the facility to	02/22/2016

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	<p>should be applied and reapplied as needed, per manufacturers' instructions, for the dwell time required to kill the targeted organism ... Cleaning and disinfection activities should be performed in a methodical pattern that limits the transmission of microorganisms. Cleaning an area in a methodical pattern establishes a routine for cleaning so that items are not missed during the cleaning process...[and]... reduce the risk of cross contamination of environmental surfaces...Process monitoring must be a part of every perioperative setting as part of an overall environmental cleaning program. Process monitoring should include...cleaning procedures, monitoring cleaning and disinfection practices, and...performance improvement should focus on thoroughness of cleaning."</p> <p>2. The policy/procedures titled Environmental Cleaning 121D (approved 11-2-15) and Cleaning, Disinfecting, Sterilization 307 (approved 5-15) failed to indicate an organized, methodical process for performing Between Case and Terminal OR cleaning to prevent contamination of previously disinfected surfaces. The cleaning and disinfecting responsibilities for the (a) the center staff, or (b) the contracted housekeeping service could not be determined to ensure</p>		<p>make sure we are cleaning and dusting according to CDC and AORN guidelines for patient safety Administrator will perform monthly walks to monitor air ducts, vents, and sprinkler heads to make sure dust is not accumulating Infection RN will report findings at the Committee meetings to makes sure protocols are being followed and recommendations will be submitted to the MAC and GB Shelving has been ordered for the janitorial closets and Cleaning supplies have been reviewed and monitored by the Infection RN Approval of the cleaning agents and EPA agents have been approved by infection committee and submitted to MAC and GB 2 Weekly monitoring by managers and Infection RN and weekly walk thrus with the QBM manager and the infection RN 3 Infection RN 4 2/20/16</p>	

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	<p>all surfaces and equipment in the restricted surgical environment and patient care areas were cleaned and disinfected on a daily or periodic basis.</p> <p>3. In interview on 2-15-16 at 1410 hours, director of nursing, staff A1, and the infection control nurse, staff A2, confirmed that the policy/procedures failed to indicate an organized process for cleaning and disinfecting to prevent contamination of previously disinfected surfaces or distinguish the responsibilities of the center staff and the contracted service.</p> <p>4. The Infection Control committee minutes dated 2-1-16 indicated that the housekeeping was monitored on 11-27-15 and the supporting document titled Audit Tool for Monitoring Infection Control Guidelines dated 11-27-15 (and completed by the director of nursing, staff A1, and the infection control nurse, staff A2) indicated the following: "Environment ...The organization has available and complies with the Centers for Disease Control and Prevention (CDC) Guidelines for Infection Control r/t (sic) environmental cleaning ...The organization has protocols in place to monitor compliance of cleanliness ...Overall appearance of the environment is satisfactory..." It could</p>			

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	<p>not be determined if the restricted surgical areas including 6 ORs, the restricted surgical hallways, the central sterile reprocessing area, the gross decontamination or the equipment storage areas were assessed on 11-27-15 and/or if the sanitation concerns identified below were present at that time.</p> <p>5. During a tour of the center on 2-15-16 at 1458 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed on the top and sides of the Steris blanket warmer in the pre-and-post operative area and the observations were confirmed by staff A1 and A2.</p> <p>6. During a tour of the center on 2-15-16 at 1505 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of a heavy accumulation of dust was observed on the 12" x 96" window sill in pre-op room #'s 2, 3 and 4 and the observations were confirmed by staff A1 and A2.</p> <p>7. During a tour of the center on 2-15-16 at 1510 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the</p>			

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	<p>presence of accumulated dust was observed on the 10" x 20" ceiling ventilation grille immediately outside the electric doors leading to the restricted surgical areas of the center and on the top of the electric door opener unit and the observations were confirmed by staff A1 and A2.</p> <p>8. During a tour of the center on 2-15-16 at 1512 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of a significant amount of accumulated dust was observed on the floor between a yellow flammable cabinet and a Steris blanket warmer upon entering the restricted surgical areas of the center and the observations were confirmed by staff A1 and A2.</p> <p>9. During a tour of the restricted surgery areas on 2-15-16 at 1515 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed in OR #4 on the wall protector or chair rail surrounding the room, on the top of the computer workstation, on the OR boom lights along the inner area of the elbow joint, and on the (2) OR return air grilles and confirmed by staff A1 and A2. It was observed that the OR boom light had</p>			

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	<p>multiple pieces of tape on the rim of the lighting unit and securing a metal access cover on the boom arm and the unsanitary practice and observations were confirmed by staff A1 and A2.</p> <p>10. During a tour of the restricted surgery areas on 2-15-16 at 1530 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed in OR #1 on the wall protector or chair rail surrounding the room, on the computer keyboard and on the (2) OR return air grilles and the observations were confirmed by staff A1 and A2.</p> <p>11. During a tour of the restricted surgery areas on 2-15-16 at 1610 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed in the procedure room #5 on the ceiling ventilation grille and the observation was confirmed by staff A1 and A2.</p> <p>12. During a tour of the restricted surgery areas on 2-15-16 at 1615 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the surgery area housekeeping closet was observed to be lacking any</p>			

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Q 0242 Bldg. 00	<p>shelving and supplies and equipment were assembled in a pile on the floor. It was observed that an EPA-approved floor cleaning and disinfecting product was not present and the observations were confirmed by staff A1 and A2.</p> <p>13. During a tour of the restricted surgery areas on 2-16-16 at 1020 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed on the 8" x 8" ceiling ventilation grille directly over the Medivator endoscope reprocessor and the observation was confirmed by staff A1 and A3.</p> <p>14. During a tour of the restricted surgery areas on 2-16-16 at 1510 hours, in the company of the director of nursing, staff A1, the presence of accumulated dust was observed in the surgical hallway leading to OR#4 and OR#6 on top of the electric door operator unit and the observation was confirmed by staff A1.</p> <p>416.51(b) INFECTION CONTROL PROGRAM The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control</p>				

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	<p>and prevent program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.</p> <p>Based on document review, observation and interview, the infection control (IC) program failed to ensure an effective cleaning process was available for patients suspected of being infected or recently diagnosed with the communicable disease Clostridium difficile (C diff) at the center.</p> <p>Findings include:</p> <p>1. The Infection Control and Hospital Epidemiology publication titled 'Strategies to Prevent Clostridium difficile Infections in Acute Care Hospitals: 2014 Update' indicated the following: "C. difficile now rivals methicillin-resistant Staphylococcus aureus (MRSA) as the most common organism to cause healthcare-associated infections (HAIs) in the United States ... [and] ... A minority of cases are diagnosed by visualizing pseudomembranes at endoscopy ... [and] ... Perform environmental decontamination of rooms of patients with Clostridium difficile using sodium hypochlorite (household bleach) diluted 1 : 10 with water or an Environmental Protection Agency (EPA) -approved</p>	Q 0242	<p>1 The Administrator met with Endoscopy physicians and Infection RN to discuss protocol for C-diff The Center will not admit any known active patients for C-diff due to the limited isolation facilities available at Our Center We only perform pediatric GI and per the Endoscopy group no patients will be admitted with Known C- diff. The Center has also approved the use of Clorox Healthcare wipes(See SDS Attachment I) to clean GI rooms and Decontam rooms for precautions with unknown communicable diseases such as C-diff. Rooms will be wiped down daily by the OR staff and Instrument Techs with both EPA agents and Clorox healthcare product Policy 121D has been updated and approved for changes in cleaning products 2 The infection control committee made recommendations to the MAC and GB for approval of Clorox Healthcare wipes they will be located in the GI ROOMS and Decontam rooms The product will be supplied by Cardinal Health. The Infection RN in-serviced all clinical staff and housekeeping on the changes to policy121D and protocol to follow for environmental contamination of clinical rooms. Infection RN</p>	02/22/2016

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	<p>sporocidal product ..."</p> <p>2. The policy/procedure Infection Control Program (approved 5-15) indicated the following: "Universal precautions will be used for all aspect of patient care in the center. If the need for patient isolation were to arise one of the enclosed patient care rooms would be utilized as an isolation area ..." and no other and no other guidelines or requirements for contact, airborne, or droplet isolation was identified.</p> <p>3. The policy/procedure Environmental Cleaning 121D (approved 11-2-15) indicated the following: "Conscientious adherence to approved cleaning and disinfection procedures, including the use of standard and contact precautions, will be expected for prevention of transmission of ... Clostridium difficile ..." and no other guidelines or requirements for contact, airborne or droplet isolation was identified.</p> <p>4. During a tour of the surgical and pre-and post-operative areas on 2-15-16 at 1450 hours, on 2-16-16 at 0930 hours, on 2-16-16 at 1510 hours and on 2-17-16 at 1500 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, no sodium hypochlorite-based cleaning</p>		and OR manager will do unannounced inspections to make sure all staff are following protocol. 3 Infection RN/OR Manager 2/22/16	

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Q 0244 Bldg. 00	<p>products or EPA-approved sporicidal products were observed and the observations were confirmed by staff A1 and A2.</p> <p>5. On 2-15-16 at 0955 hours, the director of nursing, staff A1, was requested to provide documentation indicating the center policy/procedure for contact isolation and a room cleaning process for endoscopy patients suspected or diagnosed with Clostridium difficile at the center and none was provided prior to exit.</p> <p>6. In interview on 2-17-16 at 1250 hours, the director of nursing, staff A1, and the infection prevention nurse A2, confirmed that no other documentation regarding a policy/procedure for contact isolation including a cleaning process for patients suspected or diagnosed with C diff was available.</p> <p>416.51(b)(2) INFECTION CONTROL PROGRAM - QAPI [The program is -] An integral part of the ASC's quality assessment and performance improvement program Based on document review and interview, the Quality Assessment and Performance Improvement (QAPI) program failed to ensure its infection</p>	O 0244	1 Infection RN will continue to send out monthly patient reports to all physicians for infection and complication documentation, RN after three days will call the	03/31/2016			

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	<p>control (IC) activities resulted in specific actions for improvement at the center.</p> <p>Findings include:</p> <p>1. The policy/procedure Quality Improvement and Risk Management (approved 5-15) indicated the following: " Infection Control ... Monthly a report will be directed to all physicians that have performed procedures at the facility within that month. All patient complications including infections will be reported back to the facility at that time. All complications including infections will then be reported back to the MAC (Medical Advisory Committee) after thorough investigation by the infection control officer (administrator) and committee ... Criteria for evaluation of effectiveness will be 0% of patients with post-op infections and 100% feedback from participating physicians regarding patient post-op status ... If action is determined by the QA committee and MAC it will be specifically outlined and carried out with complete documentation ... "</p> <p>2. The quarterly IC meeting minutes reporting of compliance with physician responses to monthly requests for surgical site infection tracking indicated the following:</p>		<p>physician to verbally request that the report be sent back for review if not returned. If Physicians and office do not respond, the MD who is not meeting the centers policy for reporting infections/complications will be submitted to the Medical Director for Peer Review. The third warning will be from the infection Physician representative on the committee who will recommend the MD for peer review. All reports will be expected to be returned prior to the committee meeting. A letter was sent to all active physician stating that It is mandatory that reports be returned within 3 days of receiving the form. Any Physician who does not follow protocol will be placed on Probation</p> <p>2 Follow up will be performed by Infection RN and Medical Director . Letter was sent to physicians reviewing the state regulations on reporting infections to the facility for follow up . If MD refused to report infections/complications he or she will be placed on probation and will have to go for peer review with Governing Board.</p> <p>3. Infection Committee/Infection RN 4 3/31/2016</p>		

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	<p>A. 4-21-15 "Response rate from MDs: 99% time of meeting..."</p> <p>B. 8-4-15 "Response rate from MDs: 96% time of meeting..."</p> <p>C. 11-2-15 "Response rate from MDs: 97% time of meeting..."</p> <p>No other documentation in the IC minutes dated 4-21-15, 8-4-15 or 11-2-15 indicated a discussion, recommendation or action in response to the lack of compliance with surgical site infection monitoring.</p> <p>3. The MAC meeting minutes dated 11-2-15 indicated the following: "Remind all physicians to please return infection reports in timely manner..." and no other documentation indicated how the action would be carried out by a responsible person or the expected timeframe for assuring the corrective action would result in improvement.</p> <p>4. The IC meeting minutes dated 2-1-16 indicated the following: "Response rate from MDs: 96% time of meeting..."</p> <p>5. In interview 2-17-16 at 0950 hours, the director of nursing, staff A1, confirmed the IC minutes lacked documentation of improvement in response to the concern with surgical site infection tracking.</p>			

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Q 0245 Bldg. 00	<p>416.51(b)(3) INFECTION CONTROL PROGRAM The program is - Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.</p> <p>Based on document review and interview, the infection control (IC) program failed to develop a comprehensive plan for identifying and managing infections and communicable diseases and for implementing preventive and corrective measures that result in improvement at the center.</p> <p>Findings include:</p> <p>1. The Infection Control Plan 2015 dated 3-26-15 indicated the following: "A risk assessment is the basis for this plan...Process Measures: Compliance with infection prevention protocols...Environmental cleaning and disinfection-use Glo germ in OR (operating room) and Endo (endoscopy) every 6 months...Needle stick/sharps injuries in personnel-one sharp injury..." The IC plan provided for review described an ambulatory surgery center located in Medford, Oregon on pages 1-3 and the surgical site infections reported and actions/response could not be</p>	O 0245	<p>1 Q245 (1,2) Infection Control Plan 2015 dated 3/25/15" A risk Assessment is the basis for this plan" I have no idea where this document came from, I did not copy this document for the Surveyor and until I called John Lee with ISDH I have not seen this form, Therefore I do not use GLO GERM and that is the reason I do not have any reporting in my infection minutes. I have submitted the infection control plan Policy 121 for your review as the centers control plan The infection RN will follow the policy and review quarterly in infection minutes I will not report glo germ in my minutes as I do not use the product. See attachment Policy 121 2 Q245 (1,2) IC minutes will report quarterly how the Center is monitoring Housekeeping and staff for terminal cleaning GLO GERM WILL NOT BE USED Attached Policy 121 infection control plan 3 Infection RN will report to infection committee 4 5-02-16 1. Q245 (3, 4, 5) The infection RN did fail to report the needle stick in the minutes. Protocol was followed for</p>	05/02/2016			

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	<p>attributed to the center associated with the recertification survey.</p> <p>2. Documentation of environmental IC surveillance dated 2-11-15, 3-18-15, 3-20-15, 7-22-15 and 11-27-15 and IC minutes dated 4-21-15, 8-4-15, 11-2-15 and 2-1-16 lacked documentation indicating the use of Glo germ in OR and Endo every 6 months as identified on the 2015 IC plan.</p> <p>3. Review of an incident/event report dated 4-21-15 of a needle stick injury failed to indicate the event was reviewed by the IC committee and the IC minutes dated 4-21-15 and 8-4-15 indicated the following: "Zero needle stick to report (Closed)."</p> <p>4. The MAC meeting minutes dated 4-21-15 and 8-4-15 failed to indicate a discussion, recommendation or action in response to the 4-21-15 needle stick event.</p> <p>5. In interview 2-17-16 at 1315 hours, the director of nursing, staff A1, confirmed the IC minutes lacked documentation indicating the needle stick event was reviewed.</p> <p>6. The quarterly IC meeting minutes reporting of compliance with physician</p>		<p>reporting in the OSHA 300 form and incident QM/RI was filled out. To prevent the infection committee from missing the reporting and recommendation for needle stick in the minutes, the Infection RN will bring OSHA 300 form/book to all meetings going forward. 1.Q245 (6) Infection RN will continue to send out monthly patient reports to all physicians for infection and complication documentation, RN after three days will call the physician to verbally request that the report be sent back for review. If Physicians and/or offices do not respond, the MD not meeting the centers policy for reporting infections/complications will be submitted to the Medical Director for Peer Review The third attempt will be from the infection Physician representative on the committee. All reports will be expected to be returned prior to the committee meeting. A letter was sent to all active physician stating that It is mandatory that reports be returned within 3 days of receiving the form. Any Physician who does not follow protocol will be placed on Probation and will have to go in front of Governing Board for Peer review 2 Q245 (3,4,5) Infection RN will submit the OSHA 300 book the infection committee for review and recommendations . The MAC will review the infection</p>	

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Q 0261 Bldg. 00	<p>responses to monthly requests for surgical site infection tracking indicated the following:</p> <p>A. 4-21-15 "Response rate from MDs: 99% time of meeting ..."</p> <p>B. 8-4-15 "Response rate from MDs: 96% time of meeting ..."</p> <p>C. 11-2-15 "Response rate from MDs: 97% time of meeting ..."</p> <p>D. 2-1-16 "Response rate from MDs: 96% time of meeting ..."</p> <p>No other documentation in the IC minutes dated 4-21-15, 8-4-15, 11-2-15 or 2-1-16 indicated a discussion, recommendation or action in response to the lack of compliance with surgical site infection monitoring.</p> <p>7. In interview 2-17-16 at 0950 hours, the director of nursing, staff A1, confirmed the IC minutes lacked documentation of a recommendation or corrective action for the concern with surgical site infection tracking.</p> <p>416.52(a)(1) ADMISSION ASSESSMENT Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards or practice, and ASC</p>				<p>minutes, OSHA 300 book, and incident reports to make sure nothing is missed The infection committee will retro the needle stick for review with the first qtr. infection meeting 4/26/16 2 Q245 (6,)Follow up will be performed by Infection RN and Medical Director Letter was sent to physicians stating the state regulations on reporting infections to the facility for follow up If not reported MD will be placed on probation and will have to go in front of the Governing Board for peer review 3 Infection RN-Infection Committee 4. 5-02-16</p>		

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	<p>policy. Based on document review and interview, the center failed to ensure that history and physical (H&P) examinations are completed within 30 days of admission for a procedure and updated on the day of surgery is completed for 1 of 20 medical records (MR) reviewed (patient #11).</p> <p>Findings include:</p> <ol style="list-style-type: none"> The policy/procedure Clinical Service Global Policies (approved 5-15) indicated the following: "History and Physicals (H&Ps) consistent with the scope and complexity of the procedure being performed will not be more than thirty (30) days old from the date of the procedure being performed. Updates or changes in patient's medical condition will be reviewed within 24 hours with changes noted. Any H&P not done on the day of surgery will be reviewed and updated on that day." Review of the MR for patient #11 indicated the H&P was completed on 9-10-15 and updated by the physician MD11 on 10-2-15 and on 10-27-15. On 2-17-16 at 1445 hours, the director of nursing, staff A1, and the infection control nurse, staff A2, confirmed the 	O 0261	<p>1 The one H/P was missed for the second procedure on 10/27/16 New protocol was put in place that an RN is assigned to review all H&P's 24 hours before the DOS. The RN in charge will confirm that the H&P is less than 30days old if it is past 30 days the RN will call the Physicians office and inform the MD or RN, New H&P form will be placed on the front of the Chart to inform MD to complete, All H&P's will be stamped for review and update on the DOS, Any physicians who does not comply with the policy on H&P will be presented to the MAC for peer review, 2 RN appointed in Charge of reviewing H&P 24 hours before the case will inform the MD and or the office of the expired H&P, A new H&P will be placed on the front of the chart and tag for the physician to complete before going back to the OR All H&P will be stamped on the DOS for review and update 3 PACU Manager 4/4/2016</p>	04/04/2016			

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S 0000 Bldg. 00	<p>H&P was not completed within the 30 day timeframe for the second surgery performed on the patient.</p> <p>This visit was for a State licensure survey.</p> <p>Facility Number: 004746</p> <p>Survey Date: 2/15/2016 to 2/17/2016</p> <p>QA: cjl 03/15/16</p> <p>IDR Committe held on 04-27-16. No Changes made. JL</p>	S 0000		
S 0334 Bldg. 00	<p>410 IAC 15-2.4-2.2(a)(2) QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the</p>			

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	<p>occurrence of any of the reportable events listed in subsection (a)(1) within the center in a timely manner.</p> <p>(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:</p> <p>(1) The report shall:</p> <p>(A) be made to the department;</p> <p>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program;</p> <p>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any:</p> <p>(i) patient;</p> <p>(ii) individual licensed under IC 25; or</p> <p>(iii) center employee involved;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p> <p>(A) receives a patient as a transfer; or</p> <p>(b) admits a patient subsequent to discharge;</p> <p>from another health care facility subject to a reportable event requirement. In the event that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.</p> <p>(3) The report, and any documents permitted under this section to accompany</p>			

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	<p>the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.</p> <p>(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.</p> <p>(d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually.</p> <p>(e) Any serious reportable listed in subsection (a)(1) that:</p> <p>(1) is determined to have occurred within the center between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> <p>(2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2)</p> <p>Based on document review and interview, the center lacked a process for reporting each reportable event that was determined by the quality assurance/performance improvement (QAPI) program to have occurred at the center.</p> <p>Findings:</p> <p>1. On 2/15/2016 at 10:00 AM, staff member #1 (Administrative Director) was requested to provide documentation</p>	S 0334	<p>1 Policy 118 Quality Improvement- Risk Management was revised to state the Process for reporting an Adverse event The policy will be submitted to MAC and Governing Board for approval on 5/5/16 2 Policy 118 has been reviewed and approved by the Quality improvement committee Administrator in-serviced staff on 4/20/16 with the changes made to the policy and procedure 3 Administrator 4 4/19/2016- Board approval open till 5/5/16</p>	05/05/2016

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S 0400 Bldg. 00	<p>of the process for reporting events to the Indiana State Department of Health (ISDH) and none was provided prior to exit.</p> <p>2. The policy/procedure Sentinel Event (approved 5/19/15) and Quality Improvement and Risk Management (approved 5/19/15) lacked a provision indicating the process identified by state law 410 IAC 15-2.4-2.2(a)(2) for reporting events to the ISDH.</p> <p>3. During an interview on 2/17/2016 at 1:30 PM, staff member #1 (Administrative Director) confirmed that the center lacked a policy/procedure for reporting events to the ISDH.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(a)</p> <p>(a) The center shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p> <p>Based on observation and interview, the center failed to ensure its restricted surgical environment and patient care</p>	S 0400	1 2/22/16 the Administrator, Infection RN, and OR Manager met to review our policy and housekeeping protocol for the	02/22/2016

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	<p>areas were maintained in a sanitary manner for 3 of 6 operating rooms (ORs) and the pre and post-op areas of the center.</p> <p>Findings include:</p> <ol style="list-style-type: none"> 1. During a tour of the center on 2-15-16 at 1458 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed on the top and sides of the Steris blanket warmer in the pre-and-post operative area and the observations were confirmed by staff A1 and A2. 2. During a tour of the center on 2-15-16 at 1505 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of a heavy accumulation of dust was observed on the 12" x 96" window sill in pre-op room #s 2, 3, and 4 and the observations were confirmed by staff A1 and A2. 3. During a tour of the center on 2-15-16 at 1510 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed on the 10" x 20" ceiling ventilation grille immediately outside the 		<p>facility The Policy 121D(Attachment G) was updated and awaiting approval by MAC and Governing Board Monitoring form was re-done to review the center weekly by staff and QBM (Attachment H) OR Manager, PACU manager, and BOM will perform weekly walk thru of their areas and report findings to the Infection RN QBM and the infection RN will also do weekly walks of the facility to make sure we are cleaning and dusting according to CDC and AORN guidelines for patient safety Administrator will perform monthly walks to monitor air ducts, vents, and sprinkler heads to make sure dust is not accumulating Infection RN will report findings at the Committee meetings to makes sure protocols are being followed and recommendations will be submitted to the MAC and GB Shelving has been ordered for the janitorial closets and Cleaning supplies have been reviewed and monitored by the Infection RN Approval of the cleaning agents and EPA agents have been approved by infection committee and submitted to MAC and GB 2 Weekly monitoring by managers and Infection RN and weekly walk thrus with the QBM manager and the infection RN 3 Infection RN 4 2/22/16</p>	

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	<p>electric doors leading to the restricted surgical areas of the center and on the top of the electric door opener unit and the observations were confirmed by staff A1 and A2.</p> <p>4. During a tour of the center on 2-15-16 at 1512 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of a significant amount of accumulated dust was observed on the floor between a yellow flammable cabinet and a Steris blanket warmer upon entering the restricted surgical areas of the center and the observations were confirmed by staff A1 and A2.</p> <p>5. During a tour of the restricted surgery areas on 2-15-16 at 1515 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed in OR #4 on the wall protector or chair rail surrounding the room, on the top of the computer workstation, on the OR boom lights along the inner area of the elbow joint, and on the (2) OR return air grilles and confirmed by staff A1 and A2. It was observed the OR boom light had multiple pieces of tape on the rim of the lighting unit and securing a metal access cover on the boom arm and the unsanitary practice</p>			

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	<p>and observations were confirmed by staff A1 and A2.</p> <p>6. During a tour of the restricted surgery areas on 2-15-16 at 1530 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed in OR #1 on the wall protector or chair rail surrounding the room, on the computer keyboard and on the (2) OR return air grilles and the observations were confirmed by staff A1 and A2.</p> <p>7. During a tour of the restricted surgery areas on 2-15-16 at 1610 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the presence of accumulated dust was observed in the procedure room #5 on the ceiling ventilation grille and the observation was confirmed by staff A1 and A2.</p> <p>8. During a tour of the restricted surgery areas on 2-15-16 at 1615 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the surgery area housekeeping closet was observed to be lacking any shelving and supplies and equipment were assembled in a pile on the floor. It was observed that an EPA-approved floor</p>			

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S 0404 Bldg. 00	<p>cleaning and disinfecting product was not present and the observations were confirmed by staff A1 and A2.</p> <p>9. During a tour of the restricted surgery areas on 2-16-16 at 1510 hours, in the company of the director of nursing, staff A1, the presence of accumulated dust was observed in the surgical hallway leading to OR#4 and OR#6 on top of the electric door operator unit and the observation was confirmed by staff A1.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(b)</p> <p>(b) The center shall maintain a written, active, and effective center-wide infection control program. Included in this program must be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.</p> <p>Based on document review and interview, the infection control (IC) program failed to develop and maintain an effective plan for identifying and managing infections and communicable diseases and for implementing preventive and corrective measures that result in</p>	S 0404	1 S404 (1,2) Infection Control Plan 2015 dated 3/25/15" A risk Assessment is the basis for this plan" I have no idea where this document came from, I did not copy this document for the Surveyor and until I called John Lee with ISDH I have not seen this form, Therefore I do not use	05/02/2016

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	<p>improvement at the center.</p> <p>Findings include:</p> <p>1. The Infection Control Plan 2015 dated 3-26-15 indicated the following: "A risk assessment is the basis for this plan ... Process Measures ...Compliance with infection prevention protocols ...Environmental cleaning and disinfection - use Glo germ in OR (operating room) and Endo (endoscopy) every 6 months ... Needle stick / sharps injuries in personnel - one sharp injury ..." The IC plan provided for review described an ambulatory surgery center located in Medford, Oregon on pages 1-3 and the surgical site infections reported and actions/response could not be attributed to the center associated with the recertification survey.</p> <p>2. Documentation of environmental IC surveillance dated 2-11-15, 3-18-15, 3-20-15, 7-22-15 and 11-27-15 and IC minutes dated 4-21-15, 8-4-15, 11-2-15 and 2-1-16 lacked documentation indicating the use of Glo germ in OR and Endo every 6 months as identified on the 2015 IC plan.</p> <p>3. Review of an incident/event report dated 4-21-15 of a needle stick injury failed to indicate the event was reviewed</p>		<p>GLO GERM and that is the reason I do not have any reporting in my infection minutes. The center will follow the infection control Plan Policy 121 see attachment and monitor the OR per the policy. Infection RN and OR manager will do weekly monitoring to make sure OR's and PACU are terminally cleaned properly . Infection RN will do weekly walks with Housekeeping manger to review cleaning.</p> <p>2. S404(1,2) IC minutes will report quarterly how the Center is monitoring Housekeeping and staff for terminal cleaning GLO GERM WILL NOT BE USED Attached Policy 121 infection control plan 3. Infection RN will report to infection committee 4. 5-02-16 1. S404 (3, 4, 5) The infection RN did fail to report the needle stick in the minutes. Protocol was followed for reporting in the OSHA 300 form and incident QM/RI was filled out. To prevent the infection committee form missing the reporting and recommendation for needle stick in the minutes the Infection RN will bring OSHA 300 form/book to all meeting going forward. 1.S404 (6) Infection RN will continue to send out monthly patient reports to all physicians for infection and complication documentation, RN after three days will call the physician to verbally request that the report be sent back for review if not returned. If Physicians and office</p>				

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	<p>by the IC committee and the IC minutes dated 4-21-15 and 8-4-15 indicated the following: "Zero needle stick to report (Closed)."</p> <p>4. During an interview 2-17-16 at 1315 hours, the director of nursing, staff A1, confirmed the IC minutes lacked documentation indicating the needle stick event was reviewed.</p> <p>5. The quarterly IC meeting minutes reporting of compliance with physician responses to monthly requests for surgical site infection tracking indicated the following: A. 4-21-15 "Response rate from MDs: 99% time of meeting ..." B. 8-4-15 "Response rate from MDs: 96% time of meeting ..." C. 11-2-15 "Response rate from MDs: 97% time of meeting ..." D. 2-1-16 "Response rate from MDs: 96% time of meeting ..." No other documentation in the IC minutes dated 4-21-15, 8-4-15, 11-2-15 or 2-1-16 indicated a discussion, recommendation or action in response to the lack of compliance with surgical site infection monitoring.</p> <p>6. In interview 2-17-16 at 0950 hours, the director of nursing, staff A1, confirmed the IC minutes lacked</p>		<p>does not respond, the MD not meeting the centers policy for reporting infections/complications will be submitted to the Medical Director for Peer Review The third attempt will be from the infection Physician representative on the committee. All reports will be expected to be returned prior to the committee meeting. A letter was sent to all active physician stating that It is mandatory that reports be returned within 3 days of receiving the form. Any Physician who does not follow protocol will be placed on Probation an will have to meet with Governing Board for Peer review 2 S404 (3,4,5) infection RN will submit the OSHA 300 book to the infection committee for review and recommendations The MAC will review the infection minutes, OSHA 300 book, and incident reports to make sure nothing is missed The infection committee will retro the needle stick for review with the first qtr. infection meeting 4/26/16 2 S404 (6,)Follow up will be performed by Infection RN and Medical Director Letter was sent to physicians stating the state regulations on reporting infections to the facility for follow up If not reported MD will be placed on probation and will have to meet with Governing Board for peer review 3 Infection RN-Infection Committee 4. 05/02/16</p>	

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S 0428 Bldg. 00	<p>documentation of a recommendation or corrective action for the concern with surgical site infection tracking.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(i)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(i) Sanitation. Based on document review, observation and interview, the infection control program failed to maintain its policy/procedures for environmental sanitation in accordance with accepted standards of practice for the center.</p> <p>Findings include:</p> <p>1. The Association of periOperative Nurses (AORN) Recommended Practices for Environmental Cleaning (2015) indicated the following: "Disinfectants should be applied and reapplied as needed, per manufacturers' instructions, for the dwell time required to kill the targeted organism ... Spray and misting</p>	S 0428	1 The Administrator and infection control committee met to discuss methodical protocol for cleaning Sterile areas between cases and terminal cleaning, Policy 121D (attachment G) was revised on 3/31/16 to implement a sequence for cleaning the OR rooms and sterile areas The pattern for cleaning clockwise and from top to bottom is laid out in the policy and the policy was presented to Housekeeping and staff on 4/1/16 . Cavicide Spray bottles have been removed from the Perioperative area and replaced with cavicide wipes . OR manager and PACU manager have been informed and have educated staff . OR Manager and Infection RN will monitor	04/01/2016

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	<p>methods (eg, a spray bottle) should not be used to apply cleaning chemicals in the perioperative setting ... Cleaning and disinfection activities should be performed in a methodical pattern that limits the transmission of microorganisms. Cleaning an area in a methodical pattern establishes a routine for cleaning so that items are not missed during the cleaning process... [and] ... reduce the risk of cross contamination of environmental surfaces... Process monitoring must be a part of every perioperative setting as part of an overall environmental cleaning program. Process monitoring should include ... cleaning procedures, monitoring cleaning and disinfection practices, and ... performance improvement should focus on thoroughness of cleaning."</p> <p>2. The policy/procedures titled Environmental Cleaning 121D (approved 11-2-15) and Cleaning, Disinfecting, Sterilization 307 (approved 5-15) failed to indicate an organized, methodical process for performing Between Case and Terminal OR cleaning to prevent contamination of previously disinfected surfaces or indicate a provision for process monitoring of the OR cleaning performed by (a) the center staff, and (b) the contracted housekeeping service. The cleaning and disinfecting responsibilities</p>		<p>regularly make sure no spray bottles are used in the sterile areas 2 Regular monitoring and education by the Infection RN, Infection RN will monitor weekly and monthly with staff and housekeeping. (see attachment H) Spray bottles will be removed from the OR and replaced with cavicide wipes 3 Infection RN 4 4/01/16</p>	

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	<p>for either the (a) the center staff, or (b) the contracted housekeeping service could not be determined to ensure all surfaces and equipment in the restricted surgical environment and patient care areas were cleaned and disinfected on a daily or periodic basis.</p> <p>3. During an interview on 2-15-16 at 1410 hours, director of nursing, staff A1, and the infection control nurse, staff A2, confirmed that the policy/procedures failed to indicate an organized process for cleaning and disinfecting to prevent contamination of previously disinfected surfaces or distinguish the responsibilities of the center staff and the contracted service.</p> <p>4. During an interview on 2-16-16 at 1210 hours, the infection control nurse, staff A2, confirmed that the use of spray disinfectants in the operating rooms was not recommended by the AORN.</p> <p>5. During an observation on 2-16-16 at 1430 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the use of Cavicide spray disinfectant by the OR room 1 staff while cleaning the OR was identified and the observation was confirmed by staff A1 and A2.</p>			

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S 0432 Bldg. 00	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(iii)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(iii) Cleaning, disinfection, and sterilization.</p> <p>Based on document review and interview, the infection control committee (ICC) failed to ensure its policy/procedure was followed and ensure all cleaning and disinfecting products were approved for use at the center.</p> <p>Findings include:</p> <p>1. The policy/procedure Environmental Cleaning (approved 11-15) indicated the following: "The Operations Manager and the Governing Body will approve all cleaning solutions, chemicals, and methods used at the center."</p> <p>2. On 2-15-16 at 0930 hours, the director of nursing, staff A1, was requested to provide documentation of approved cleaning and disinfecting products for use</p>	S 0432	<p>1 The infection RN and Administrator met to review all cleaning products used in facility from staff and housekeeping The Following items were reviewed and approved by the infection committee and recommended to the MAC and Governing Board : (Cavicide Wipes (EPA), Clorox healthcare wipes, Stainless steel polish and cleaner by Clair manufacturer, Crew clinging toilet bowl cleaner by Diversey, Glance RTU glass and multi surface cleaner, and Virex II one Step Disinfectant(EPA) All products were reviewed with Housekeeping and infection RN, discussed where each item is used, Infection RN discussed and educated housekeeping and staff on usage and time to leave product on surface before wiping clean and the methodical process to follow</p> <p>2 Infection RN presented the</p>	03/31/2016			

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S 0438 Bldg. 00	<p>at the center and none was received prior to exit.</p> <p>3. During an interview on 2-17-16 at 1240 hours, the director of nursing, staff A1, and the infection control nurse A2, confirmed that a list of approved cleaning and disinfecting products or documentation of cleaning products that were approved by the ICC and/or governing body was not available.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(vi)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(vi) A patient isolation system. Based on document review and interview, the infection control (IC) program failed to ensure an effective cleaning process was available for patients suspected of being infected or recently diagnosed with the communicable disease Clostridium difficile (C diff) at the center.</p>	S 0438	<p>cleaning products to infection committee and recommended the products to the MAC and Governing Board for approval, Products will be reviewed on a regular basis and approval annually with MAC and GB, Any changes to cleaning products must go through infection RN before a change can be made no products can be used unless approved by infection committee, MAC and GB 3 Infection RN 4 3/31/16</p> <p>1 The Administrator met with Endoscopy physicians and Infection RN to discuss protocol for C-diff The Center will not admit any known active patients for C-diff due to the limited isolation facilities available at Our Center We only perform pediatric GI and per the Endoscopy group no patients will be admitted with Known C- diff. The Center has also approved the use of Clorox</p>	02/22/2016

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	<p>Findings include:</p> <p>1. The Infection Control and Hospital Epidemiology publication titled ' Strategies to Prevent Clostridium difficile Infections in Acute Care Hospitals: 2014 Update ' indicated the following: "C. difficile now rivals methicillin-resistant Staphylococcus aureus (MRSA) as the most common organism to cause healthcare-associated infections (HAIs) in the United States ... [and] ... A minority of cases are diagnosed by visualizing pseudomembranes at endoscopy ... [and] ... Perform environmental decontamination of rooms of patients with Clostridium difficile using sodium hypochlorite (household bleach) diluted 1 : 10 with water or an Environmental Protection Agency (EPA) -approved sporicidal product ..."</p> <p>2. The policy/procedure Infection Control Program (approved 5-15) indicated the following: "Universal precautions will be used for all aspect of patient care in the center. If the need for patient isolation were to arise one of the enclosed patient care rooms would be utilized as an isolation area ..." and no other and no other guidelines or requirements for contact, airborne, or droplet isolation were identified.</p>		<p>Healthcare wipes(See SDS Attachment I) to clean GI rooms and Decontam rooms for precautions with unknown communicable diseases such as C-diff. Rooms will be wiped down daily by the OR staff and Instrument Techs with both EPA agents and Clorox healthcare product Policy 121D has been updated and approved for changes in cleaning products 2 The infection control committee made recommendations to the MAC and GB for approval of Clorox Healthcare wipes they will be located in the GI ROOMS and Decontam rooms The product will be supplied by Cardinal Health. The Infection RN in-serviced all clinical staff and housekeeping on the changes to policy121D and protocol to follow for environmental contamination of clinical rooms. Infection RN and OR manager will do unannounced inspections to make sure all staff are following protocol. 3. Infection RN/OR Manager 4. 2/22/16</p>	

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S 0444	<p>3. The policy/procedure Environmental Cleaning 121D (approved 11-2-15) indicated the following: "Conscientious adherence to approved cleaning and disinfection procedures, including the use of standard and contact precautions, will be expected for prevention of transmission of ... Clostridium difficile ..." and no other guidelines or requirements for contact, airborne or droplet isolation were identified.</p> <p>4. On 2-15-16 at 0955 hours, the director of nursing, staff A1, was requested to provide documentation indicating the center policy/procedure for contact isolation and a room cleaning process for endoscopy patients suspected or diagnosed with Clostridium difficile at the center and none was provided prior to exit.</p> <p>5. During an interview on 2-17-16 at 1250 hours, the director of nursing, staff A1, and the infection prevention nurse A2, confirmed that no other documentation regarding a policy/procedure for contact isolation including a cleaning process for patients suspected or diagnosed with C diff was available.</p> <p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM</p>						

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Bldg. 00	<p>410 IAC 15-2.5-1(f)(2)(E)(ix)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.</p> <p>Based on document review, observation and interview, the infection control program failed to ensure its policy/procedures for surgical attire were consistent with acceptable standards of practice.</p> <p>Findings include:</p> <ol style="list-style-type: none"> The Association of periOperative Nurses (AORN) Recommended Practices for Surgical Attire (2015) indicated the following: "Surgical Masks ... Replace and discard the mask whenever it becomes wet or soiled, or has been taken down ..." The policy/procedure Infection Control Program (approved 5-15) indicated the following: "All persons entering restricted areas of the surgical suite should wear masks when there are 	S 0444	<p>1 Infection RN and Administrator met with all staff to discuss protocol for removing mask before they leave the OR unless otherwise recommended when transferring a patient to the Recovery, Transport team MUST remove and discard dirty mask before they leave the bedside in Recovery. Mask must remain up if needed for transport, no mask are allowed to dangle from the neck after a physician or staff member leaves the surgical suite (See Policy 121 Attachment J) 2 Policy 121 was revised and presented to staff and Physicians Managers are to monitor staff, physicians, and Anesthesia to remind them to remove mask before leaving the surgical suite Staff and Physicians 1st violation will be given a warning, 2nd violation they will receive a written warning, if third violation occurs the physician and staff will go in front</p>	04/17/2016

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S 1146 Bldg. 00	<p>open sterile items and equipment present..." and no other guidelines or requirements for use of surgical masks was identified.</p> <p>3. During a tour of the center on 2-16-16 at 0915 hours, in the company of the director of nursing, staff A1, and the infection control nurse, staff A2, the physician MD13, the physician MD14, and the physician MD15 were observed to enter the pre-operative area with a surgical mask tied around the neck and down on the chest area and the observations were confirmed by staff A1 and A2.</p> <p>4. During an interview on 2-16-16 at 1410 hours, of the director of nursing, staff A1, confirmed the policy/procedure lacked a requirement to discard the surgical mask when taken down.</p> <p>410I AC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(2)</p> <p>(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(2) No condition may be created or</p>		<p>of peer review committee for recommendaions. Peer review will be involved if the policy is not enforced and presented to the MAC/Medical Director and GB for recommendations, Managers will discuss with staff and termination will occur is policies are not followed 3 Administrator 4 4/17/16</p>		

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	<p>maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on document review and interview, the facility failed to ensure three (3) of five (5) operating rooms met 15 air exchanges per hour.</p> <p>Findings included:</p> <ol style="list-style-type: none"> On 2/15/2016 at 10:00 AM, staff member #1 (Administrative Director) was requested to provide documentation of operating room air exchanges provided to five operating rooms (OR) and only 4 of 5 operating rooms documentation was provided. Review of Room Ventilation Survey Reports indicated "operating rooms are required to provide 15 air exchanges per hour." Three of four operating room (OR 1, OR 2 and OR 3) documentation that was provided did not meet the required 15 air exchanges per hour and the facility did not provide documentation for operating room #6: <ol style="list-style-type: none"> OR 1 - 11.9 air exchanges per hour. OR 2 - 12.4 air exchanges per hour. OR 3 - 5.5 air exchanges per hour. OR 4 - 17.8 air exchanges per hour. OR 6 - No Ventilation Survey Report available. 	S 1146	<p>The Facility Administrator notified Diversified Anesthesia to better understand Air exchange reports Center has never been cited for Air Exchange issues and felt she needed clarification Per our representative from Diversified Anesthesia our air exchanges meet CMS/State requirements Please see attached forms Center did notify Freije to let them know that they did not report appropriately our ventilation for OR6 Diversified came out on 4-6-16 to do another test on the Air exchanges in OR 6(See attachment A) Per Brandon you add the two numbers together to read the air exchanges (See attachment A for the results ie OR 1 11'9+45'6= 57'5 air exchange 2 Diversified stated that if there ever was an issue I would be notified immediately of any problems Administrator had Brandon in-service her on how to read the report appropriately. 3 Administrator reported in the infection control committee 4 04/6/2016 next inspection will be for all the OR May 6, 2016</p>	04/06/2016

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	3. In interview at 1:55 PM on 2/17/2016, staff member #1 confirmed the above and no other documentation was provided by exit.				