

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 12/16/2011
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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 1 CARMEL, IN46032
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S0000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 004746</p> <p>Survey Date: 12/15/2011 through 12/16/2011</p> <p>Surveyors: Saundra Nolfi, RN Public Health Nurse Surveyor</p> <p>Albert Daeger Medical Surveyor</p> <p>QA: claughlin 01/04/12</p>	S0000		
S0153	<p>410 IAC 15-2.4-1(c) (5) (C)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.</p> <p>Based on document review and interview, the facility failed to ensure the employees of the contracted housekeeping service</p>	S0153	1. New training and competency form was developed by infection committee on 1/16/2012. The	01/16/2012

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>received initial job-specific orientation and competency for all 5 staff members (#H1-5).</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Documentation in the binder for the contracted housekeeping company indicated a signed contract beginning the service on February 19, 2008. The contract specified that Virex Disinfectant or other comparable product would be used, but failed to address any other chemicals such as the ones that were observed during the tour. 2. Review of the employee information in the binder failed to indicate any documentation of initial orientation or specific job competencies for any of the 5 housekeeping employees, #H1- 5. 3. The binder lacked any documentation of any specific process or order for cleaning or specific chemicals to be used. 4. At 1:45 PM on 12/15/11, the contracted housekeeping staff manager, staff member #H1, indicated he/she oriented each employee to the specific facility and process of cleaning, but confirmed there was no written documentation of this process. He/she also confirmed there was no written 		<p>form is waiting for approval from Medical advisory and Governing Board. Housekeeping will receive orientation/training on 1-23-12. The expected competencies and chemicals to be used for environmental cleaning will be discussed with Housekeeping and staff. All documentemation will be placed in the Housekeeping Binder. 2. Quarterly the infection RN will monitor housekeeping and question their technique and responses on the chemicals they are using, and their method of cleaning. Infection RN Will fill out APIC form for each random review. Staff will also be monitored monthly on the appropriate use of chemicals for environmental cleaing and the techniques for mixing the chemicals/gallon of water. Addendum: Training will take place on 1/23/12. The new orientation form was developed on 1/16/12. 3. Infection RN/OR Manager</p>		

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S0432	<p>process for mixing the chemicals or which ones to use in different areas.</p> <p>5. At 2:05 PM on 12/16/11, staff member #P2, indicated the binder contained all of the documentation the facility had for the housekeeping staff and confirmed the lack of documentation of initial orientation and job specific competency.</p> <p>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 observation, manufacturer's literature, and interview, the infection control program failed to ensure chemicals were used appropriately in the surgical area.</p> <p>Findings included:</p> <p>1. At 4:25 PM on 12/15/11, accompanied by the manager of the contracted cleaning service, staff member #H1, a gallon of</p>	S0432	<p>1. Housekeeping and staff were all inserviced on the proper mixing of all Quaternary disinfectant cleansers. Appropriate measurement cups marked with nail polish were placed in each Janitors closet and in Decontam. How to mix cleansers for all products have been placed in each of the Janitors closets and in Decontam. All staffed signed off that they know how to mix each of the Quaternary disinfectant</p>	12/28/2011			

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	<p>bleach, a 2-gallon container of 70% isopropyl alcohol and a gallon container of Quaternary Disinfectant Cleaner were observed in the janitor's closet for the surgical suites. No measuring devices were observed in the room.</p> <p>2. At 12:15 PM on 12/16/11, a mop bucket containing a mop and clear, reddish-colored solution was observed in the surgical corridor.</p> <p>3. At 12:20 PM on 12/16/11, accompanied by staff member #P19, the set up to clean used instruments in the decontamination room was observed. Staff member #P19 put 2 squirts of NpH Klenz in the left side of a 2-compartment sink and filled the sink with water to a marking on the sink. Staff member #P19 put 2 squirts of GI-zyme in the right sink compartment and filled the sink with water, not to any premarked lines.</p> <p>4. Staff member #P19 indicated the marking on the sink was to be 2 gallons.</p> <p>5. The manufacturer's directions on the Quaternary Disinfectant cleaner were to mix 2 ounces of disinfectant to each gallon of water to achieve the proper concentration for disinfection in the surgical areas.</p>		<p>cleaners. Alcohol and Bleach mixtures were confirmed with housekeeping and the appropriate mixing methods. MSDS sheets were placed in our Facility book and in The Housekeeping manual.2. Deficiencies will be monitored monthly until infection committee feels that all housekeeping and staff are comfortable with measuring the disinfectants per gallon of water. OR Manager and Infection RN will do random spot checks. Yearly staff will review products and how to mix solutions.3. Infection RN and OR Manager</p>		

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	<p>6. The manufacturer's directions on the NpH Klenz were to mix 1/8 to 2 ounces of solution to each gallon of water. The directions on the GI-zyme were to mix 1/2 ounce per gallon of water.</p> <p>7. At 4:25 PM on 12/15/11, staff member #H1 indicated the floors of the surgical area were mopped with the Quaternary Disinfectant Cleaner mixed in water. He/she indicated the concentration was 2 1/2 teaspoons per gallon of water. He/she indicated a marking on the bucket that was 4 gallons and indicated 5 teaspoons of the disinfectant would be used for that amount. Measuring devices were kept in another janitor's closet to which he/she did not have a key. He/she indicated the supervisor mixed the solution from that closet for the other staff members to use. Staff member #H1 also indicated the bleach was used to whiten the mop heads as needed and the alcohol was used for the glass in the doors to the operating suites. He/she confirmed there were no directions regarding mixing these solutions.</p> <p>8. At 12:15 PM on 12/16/11, staff member #P19 indicated he/she measured the Quaternary Disinfectant Cleaner and mixed up the mop solution each day for the staff to use between cases in the surgical suites. He/she indicated a plastic</p>				

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	<p>specimen container that was now in the janitor's closet. At 3 different times during the interview, staff member #P19 indicated the measurement indicating 40 milliliters on the container was the amount of disinfectant added to 4 gallons of water in the bucket. There were no handwritten marks on the container, just the manufacturer's original measurement markings. He/she also indicated 2 squirts of both of the instrument cleaning solutions were equal to 2 ounces and that was what he/she used to each gallon of water in the sinks in the decontamination room.</p> <p>9. At 12:45 PM on 12/16/11, staff member #P12 indicated staff member #P19 mixed the mop water for them, but left a measuring cup with markings in case other staff members had to mix it up. He/she indicated the concentration was 2 1/2 ounces of disinfectant per gallon of water.</p> <p>10. At 2:05 PM on 12/16/11, staff member #P10 on site and staff member #P2 via telephone, confirmed the discrepancies regarding the mixing of the disinfectant solution, both with facility staff and with the contracted cleaning service.</p>				

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S0442	<p>410 IAC 15-2.5-1(f)(2)(E)(viii)</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>(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>Based on policy review, personnel file review and interview, the facility failed to ensure the immunization status of the staff was verified for 7 of 14 employees reviewed (#P2, P4, P6, P10, P12, P13, and P14).</p> <p>Findings included:</p> <p>1. Review of employee health records failed to indicate documentation of Varicella immunity for staff members #P2, P4, P6, P10, P12, P13, and P14.</p> <p>2. The facility's Infection Control Program, last revised on 05/09/11, stated on page 5, ..."Employee Health Program, Immune Status, Immunization history for all employees will be documented in their</p>	S0442	<p>1. Managers and Administrator reviewed all staff health records and those born after 1957 will have a titer drawn for varicella from MidAmerica clinical laboratories.2. All new staff will have a pre-printed blood work form from MidAmerica with the communicable diseases that require immunization or titer. This will only be drawn if the employee does not have proof of immunization.Addendum: Policy 121 has been revised to state that proof of Immunizations (Rubeola, Rubella, and Varicella) will be placed in each of the employee health records.Communicable Disease HistoryRubeola, Rubella and Varicella Proof of immunizations.Titer will be Drawn by MidAmerica if an employee is not able to show proof of immunization. All Records will be</p>	01/13/2012

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	<p>health record." The document continued with "Communicable Disease History", but only addressed tuberculosis, not any other diseases.</p> <p>3. At 1:00 PM on 12/15/11, staff member #P2 indicated he/she was aware that immunization status should include Rubella, Rubeola, and Varicella and thought titers were being obtained for those diseases.</p>		<p>placed in the Health File3. OR/PACU manager and infection control committee</p>		

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S0772	<p>410 IAC 15-2.5-4(b)(3)(M)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(M) A requirement that a medical history and physical examination be performed as follows:</p> <p>(i) In accordance with medical staff requirements on history and physical consistent with the scope and complexity of the procedure to be performed.</p> <p>(ii) On each patient admitted by a physician, dentist, or podiatrist who has been granted such privileges by the medical staff or by another member of the medical staff.</p> <p>(iii) Within the time frame specified by the medical staff prior to date of admission and documented in the record with a durable, legible copy of the report and with an update and changes noted in the record on admission in accordance with center policy.</p> <p>Based on policy review, medical record review and interview, the facility failed to ensure the History and Physicals were performed and dated according to policy for 5 of 18 patient records reviewed (#N6, N12, N13, N16, and N18).</p> <p>Findings included:</p>	S0772	<p>1. The Staff, Physicians and Scheduler were all informed that H&P must be on the chart prior to going to the OR. All Staff, Physicians, and offices were informed that the H&P must be less then 30 days old and updated on the Date of Service. The PACU Manager will monitor charts daily and do a QA Study on 30 charts each month for 100% Compliance according</p>	01/09/2012	

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	<p>1. The facility policy titled "Clinical Service Global Policies", last revised 05/09/11, stated under History and Physicals, ..."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 any changes noted. Any H & P not done the day of surgery will be reviewed and updated on that day."</p> <p>2. The medical record for patient #N6, who had a procedure on 10/11/11, indicated a history and physical form that had been faxed to the facility on 10/08/11. In the space for "Date of exam", 10/11/11 was written in, but a stamp of "H&P Updated" was dated 10/25/11.</p> <p>2. The medical record for patient #N16, who had a procedure on 10/17/11, indicated a history and physical form dated 8/26/11, over 30 days prior to the procedure. A stamp of "H&P Updated" was signed by the physician, but not dated.</p> <p>3. The medical record for patient #N13, who had a procedure on 08/30/11, indicated a history and physical form with</p>		<p>to the policy and state guidelines.</p> <p>2. Daily check by the PACU manager and/or a designated RN. PACU Manager will perform monthly study on 30 charts for H&P complete, Less then 30days old, and updated with signature and date on the DOS. QA studies goal is 100%.3. All Staff, Physicians, Medical Records, PACU Manager.</p>	

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S1010	<p>no date in the space, "Date of Examination". A stamp of "H&P Updated" was dated 08/30/11, but not signed by the physician.</p> <p>4. The medical record for patient #N16, who had a procedure on 06/17/11, indicated a history and physical dated June 01, 2011. A stamp of "H&P Updated" was signed by the physician, but not dated.</p> <p>5. The medical record for patient #N18, who had a procedure on 02/03/11, indicated a history and physical dated 01/10/2011. A stamp of "H&P Updated" was signed by the physician, but not dated</p> <p>6. At 3:55 PM on 12/16/11, the medical record findings were confirmed by staff member #P10.</p> <p>410 IAC 15-2.5-6(3)(A)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on observation, policy review and</p>	S1010	1. Staff and PACU manager	12/19/2011			

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	<p>interview, the facility failed to follow their policy regarding multi-dose vials in 1 of 1 open vials observed.</p> <p>Findings included:</p> <p>1. During the tour of the facility at 10:00 AM on 12/16/11, accompanied by staff members #P2 and P10, an open, but not dated, 20 milliliter vial of Labetalol Hydrochloride for injection was observed in an upper cabinet in the medication room.</p> <p>2. The facility Medication Policy, last reviewed 10/18/11, stated on page 3, ..."Multi-dose vials: Is a bottle of liquid medication (injectable) that contains more than one dose of medication and approved by the FDA for use on multiple persons: will be refrigerated, if necessary, discarded after 28 days of the vial being opened or when empty or upon the expiration date set by the manufacturer."</p> <p>3. At 10:00 AM on 12/16/11, both staff members #P2 and P10 indicated the multi-dose vials should be dated when opened and discarded after 28 days.</p>		were informed of the open vial of Labetalol. Reviewed with Staff Medication policy about open MDV vials being dated for 28days after being opened. 2. Random spot checks will be done by Managers to assure that all MDV vials are dated appropriately once they are opened. They will also monitor that MDV vials are discarded after 28 days or according to Manufacturers recommendations.3. OR Manager/PACu Manager		

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S1146	<p>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 maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on observation, documentation review and staff interview, the facility failed to maintain free obstruction to a fire exit for the hallway adjacent to Pre-op, failed to maintain Material Safety Data Sheet (MSDS) sheets for two chemicals that were used in OR and Pre-op and failed to ensure out-of-lab testing supplies were dated to prevent out-dated use and the possibility of inaccurate readings.</p> <p>Findings included:</p> <p>1. The Surgery Center of Carmel Quality Improvement and Risk Management policy #118 states, "The Center will monitor at a minimum compliance with performance standards determined by federal, state, and local authorities..."</p> <p>2. NFPA 101 Means of Egress Reliability 7.1.10.1 states, "Means of egress shall be continuously maintained free of all</p>	S1146	<p>1.A.) Unfortunately circumstances prevented the Green linen carts from being placed in the appropriate area. 11:00 AM with inspector watching the Administrator moved the line carts to the Pre op area. The carts were placed along the west wall with 70 inches of clearance to the exit door. The Step down unit which houses the linen carts was being utilized by AAAHC. Carts are placed in the appropriate area every Friday upon delivery. Linen is removed from the carts when staff are done with patient care. B.) A MSDS sheet was placed in the book for both Bleach and Febreze. C.) LABs controls were all reviewed with PACU staff and OR staff. Procedures were typed up to follow. All procedures are performed according to manufacturers recommendations. Annually staff will complete competency and explain how controls should be dated and stored and when they</p>	12/21/2011			

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	<p>obstructions or impediments to full instant use in the case of fire or other emergency."</p> <p>3. At 9:45 AM on 12/16/2011, the linen company was observed delivering 2 large green linen storage carts filled with clean linen. The two green linen carts were placed in the hallway adjacent to Pre-op. The carts obstructed the accessibility to the fire exit door leading to the outside of the building that was clearly illuminated with a Fire Exit sign. The hallway was 48 inches wide and the fire exit door was 36 inches wide. The linen storage units were 30 inches wide by 60 inches long. At 12:00 PM, the 2 green linen storage carts were still obstructing the accessible pathway to the fire exit door.</p> <p>4. At 12:05 PM on 12/16/2011, staff member #2 indicated the linen storage carts would be removed and the linen would be stocked at the end of the day after the last surgery was completed.</p> <p>5. Physical Plant, Equipment Maintenance, Environmental Service, Emergency Action Plan policy #120 states, "A material safety data sheet (MSDS) will be obtained for all chemicals that have an MSDS available from the manufacturer. The MSDS sheets will be readily accessible during work hours so</p>		<p>should be discarded.2. A.) Carts are placed in the Step down area every Friday.Addendum: Administrator Informed all staff that Linen must be placed in Linen Room every Friday. No Carts can be left in Hallway blocking the Exit door. PACU Manager will monitor weekly that Green carts are placed in the linen Room. B.) Administrator will monitor all new chemicals that enter the facility and place an MSDS sheet in the binder. Staff will review the Binder yearly or as needed. C.) PACU Manager or designated RN will inservice all existing and new staff members on the controls, manufacturers protocol for dating, storing, and discarding. Annually staff will be inserviced on the controls and their competency.3. A.) Administrator and all staff B.) Administrator C.) PACU Manager</p>		

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 12/16/2011
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	<p>that employees can immediately obtain required information in an emergency situation."</p> <p>6. At 10:00 AM on 12/16/2011, the OR janitor's closet was inspected and there was a gallon of bleach observed in the room.</p> <p>7. At 12:30 PM on 12/16/2011, an aresol container of 'Febreeze' (odor control chemical) was observed on a Pre-op wire storage rack.</p> <p>8. The MSDS manual was provided by staff located in the medical records area. The MSDS manual had an inventory list of all chemicals used in the facility. Neither the chemical bleach nor Febreeze had an MSDS sheet. Administrative staff did not provide a MSDS sheet for the 2 chemicals observed in the facility.</p> <p>9. During the tour of the facility at 10:10 AM on 12/16/11, accompanied by staff members #P2 and P10, the following observations were made in the clean room of the pre-op area:</p> <p>A. Stat-Site hemoglobin controls, 6 bottles were open, but not dated, in the refrigerator.</p> <p>B. An open, empty, but not dated, container of Stat-Site M strips with a</p>			

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	<p>manufacturer's expiration date of 05/2011. (The strips had just been used to do the control testing.)</p> <p>C. Two open, but not dated bottles of control solution for urine pregnancy testing.</p> <p>D. An open container of Hemocue strips for glucose testing with handwritten dates of 12/14/11 as opened and 01/11/12 as expiration date. The manufacturer's expiration date on the container was 12/29/11.</p> <p>10. Review of the manufacturer's literature indicated the following:</p> <p>A. The Stat-Site hemoglobin controls were to be stored in the refrigerator and discarded 60 days after opening.</p> <p>B. The Stat-Site M strips were to be discarded 90 days after opening.</p> <p>C. The control solution for the urine pregnancy testing was to be discarded 90 days after opening.</p> <p>D. The Hemocue strips were to be dated when opened and could be stored at room temperature for 3 days or in the refrigerator for 30 days.</p>				

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		S1146	<p>1.A.) Unfortunately circumstances prevented the Green linen carts from being placed in the appropriate area. 11:00 AM with inspector watching the Administrator moved the line carts to the Pre op area. The carts were placed along the west wall with 70 inches of clearance to the exit door. The Step down unit which houses the linen carts was being utilized by AAAHC. Carts are placed in the appropriate area every Friday upon delivery. Linen is removed from the carts when staff are done with patient care. B.) A MSDS sheet was placed in the book for both Bleach and Febreze. C.) LABs controls were all reviewed with PACU staff and OR staff. Procedures were typed up to follow. All procedures are performed according to manufacturers recommendations. Annually staff will complete competency and explain how controls should be dated and stored and when they should be discarded.2. A.) Carts are placed in the Step down area every Friday.Addendum: Administrator Informed all staff that Linen must be placed in Linen Room every Friday. No Carts can be left in Hallway blocking the Exit door. PACU Manager will monitor weekly that Green carts are placed in the linen Room. B.) Administrator will monitor all new chemicals that enter the facility and place an</p>	12/21/2011	

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