

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001123	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 02/11/2014
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NAME OF PROVIDER OR SUPPLIER CLI SURGERY CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 7747 W JEFFERSON BLVD STE B FORT WAYNE, IN 46804
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Q000000	The visit was for a re-certification survey. Facility Number: 003375 Survey Date: 2-10-14 to 2-11-14 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor QA: claughlin 02/17/14	Q000000		
Q000084	416.43(e) GOVERNING BODY RESPONSIBILITIES The governing body must ensure that the QAPI program- (1) Is defined, implemented, and maintained by the ASC. (2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness. (3) Specifies data collection methods, frequency, and details. (4) Clearly establishes its expectations for safety. (5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program. Based on document review and interview, the governing body failed to	O000084	The Facility Administrator will be responsible for scheduling the	04/15/2014

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>ensure that the quality assessment and improvement (QA&I) program maintained its standards and allocated sufficient resources to address the QA&I program priorities for patient safety.</p> <p>Findings:</p> <ol style="list-style-type: none"> The Medical Staff Bylaws (approved 1-13) indicated the following: "...Committees of the Medical Staff: QA&I Committee ...shall consist of the chief executive officer (CEO), the Medical Director or his/her designee ... (and) ...the Director of Anesthesia The QA&I committee shall review ...any surgical case ... [involving] ...a patient's marked deterioration in condition following unanticipated or unexpected circumstances...and maintain a permanent written record of its proceedings and actions..." Center documentation indicated that MD11 was the center CEO and a governing board member with financial interest in the center. QA&I committee minutes dated 1-17-13, 4-25-13, 7-01-13, 10-17-13 and 1-16-14 failed to indicate that the CEO attended the last five meetings. During an interview on 2-11-14 at 		<p>medical staff meetings quarterly and will ensure that the CEO or his designee will be in attendance. The next meeting is scheduled for April 15, 2014. The Facility Administrator added discharges, transfers, medication errors and response to patient emergencies to the QAP&I template and will be reported during the quarterly meeting. The Facility Administrator met with the DON on 2/19/14 and the DON will be responsible for ensuring that these cases are peer reviewed so that actions and outcomes are implemented if necessary. The Facility Administrator will ensure ongoing compliance. During the quarterly QAP&I meeting all issues and/or concerns from the previous meeting will be discussed and reviewed. Any action discussed will be documented as well as the outcome. If the action was not implemented the item will be discussed and placed on the agenda for the next meeting with a new action documented.</p>	

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Q000123	<p>1220 hours, the administrator A1 confirmed that the CEO failed to attend the last 5 quarterly QA&I committee meetings.</p> <p>5. Center documentation indicated one patient transfer in 2013 and the QA&I program documentation failed to indicate that the patient safety event was investigated and/or indicate a committee action to prevent additional occurrences.</p> <p>6. QA&I peer review documentation failed to indicate a finding that the care was appropriate and/or indicate a recommendation(s) for improvement.</p> <p>7. During an interview on 2-11-14 at 1415 hours, administrator A1 confirmed that QA&I program failed to document a review and response to the 2013 patient transfer.</p> <p>416.45(c) OTHER PRACTITIONERS If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities. Based on document review and interview, the center failed to assure that allied health professionals (AHP) were reappointed in accordance with its</p>	O000123	<p>On 2/24/14 the Facility Administrator sent the Medical Staff Bylaws, rules and regulations to all CRNA's that are</p>	03/14/2014			

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Q000220	<p>medical staff bylaws for 1 allied health professional (AH21) file reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The Medical Staff Bylaws (approved 1-13) indicated the following: " Any individual who desires to obtain AHP privileges in the ASC shall submit an application for employment or an application for privileges, as applicable ... [including] ...the express statement of the applicant that he/she has read, understands, and agrees to abide by the Medical Staff Bylaws and Rules and Regulations ... " 2. Review of the credential file for Certified Registered Nurse Anesthetist (CRNA) staff AH21 failed to indicate a signed statement that the CRNA agreed to abide by the medical staff bylaws, rules and regulations as a condition for granting of privileges by the governing board. 3. During an interview on 2-11-14 at 1620 hours, administrator A1 confirmed that the credential file lacked the required documentation. <p>416.50 NOTICE - POSTING ... The ASC must also post the written notice</p>		<p>credentialed</p> <p>in the center. A signed acknowledgement</p> <p>will be placed in their files by 3/14/14.</p> <p>The Facility Administrator will be responsible to ensure this has been</p> <p>completed by 3/14/14.</p>	

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Q000221	<p>of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable. Based on observation and interview, the center failed to ensure that the posted patient rights document included 6 of 14 required elements.</p> <p>Findings:</p> <p>1. During an observation on 2-11-14 at 1545 hours, the patient rights document posted in the reception area failed to indicate the following patient rights:</p> <ul style="list-style-type: none"> a. written notice of the physicians who have financial interest or ownership in the ASC center. b. the center must provide a copy of the official State advanced directive forms upon request. c. all grievances related to (but not limited to): mistreatment, neglect, verbal, mental, sexual and/or physical abuse must be fully documented and immediately reported to person in authority and substantiated allegations reported to the State authority and/or local authority. d. the right to exercise his or her rights without being subjected to discrimination or reprisal. e. the right to submit grievances regarding treatment or care that is (or fails to be) furnished. f. the right to be free from all forms of abuse, neglect or harassment from staff, other patients, or visitors. <p>2. During an interview on 2-11-14 at 1545 hours, staff A1 confirmed that the posted rights lacked the indicated patient rights.</p> <p>416.50(a) NOTICE OF RIGHTS</p>	0000220	<p>On 2/26/14 the Facility Administrator revised the posted written notice of the patient rights and responsibilities to include the 6 elements missing from our current posting. These revisions will be reviewed by the Compliance Officer by 3/14/14 and will be reviewed by the Medical Staff on 4/15/14 and the Governing Body on 4/18/14. The updated posting will be posted on 4/21/14.</p>	04/21/2014

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	<p>An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.</p> <p>Based on patient medical record review and interview, the facility failed to ensure that patients were presented with copies of their rights prior to each surgical procedure for 2 of 2 patients with a second surgery performed (pts. #9 and #10).</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. review of patient medical record #9 indicated: <ol style="list-style-type: none"> a. the patient had a second surgery on 11/14/13 b. the patients' rights form and document with advance directive information and physician ownership were signed on 9/6/13 for the first surgery 2. review of patient medical record #10 indicated: <ol style="list-style-type: none"> a. the patient had a second surgery on 11/14/13 	0000221	<p>During a staff meeting dated 2/24/14 the Director of Nursing retrained the staff on obtaining a new signed patient rights and responsibilities for every procedure. On 2/26/14 the Facility Administrator made a revision to the Patient Rights and Responsibilities Policy to state the following: "A copyof the patient's rights is posted in the Center lobby and must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site of the Office of the Medicare Beneficiary Ombudsman. Prior to the start of the procedure the Center will provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights, notice of ownership and advance directives in a language and manner that ensures the patient, the representative, or the surrogate understand all of the</p>	04/18/2014

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Q000224	<p>b. the patients' rights form and document with advance directive information and physician ownership were signed on 9/4/13 for the first surgery</p> <p>3. interview with staff member #62, the facility administrator, at 4:20 PM on 2/11/14, indicated:</p> <p>a. the facility policy related to patients' rights does not indicate that a copy of the patient rights, physician ownership, and advance directives must be given prior to each surgical procedure performed</p> <p>b. it was unknown that these documents must be provided with each procedure</p> <p>416.50(c)(1)(2)(3) ADVANCED DIRECTIVES 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</p>		<p>patient's rights. A copy will be placed in the medical record." These revisions/additions to the policy will be reviewed by Compliance Officer by 3/14/14 the Medical Staff on 4/15/14 and the Governing Body on 4/18/14. The staff will be trained on this policy once it has been approved during their April staff meeting. The Director of Nursing will be responsible for ensuring this training is completed.</p>	

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	<p>patient's current medical record, whether or not the individual has executed an advance directive.</p> <p>Based on document review and interview, the policy/procedure Advance Directives failed to assure that a copy of the Indiana State Advanced Directives brochure was provided to patients if requested and failed to assure the medical record (MR) prominently documented whether or not the patient had executed an advance directive.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The policy/procedure Patient Rights (approved 12-11) and Advanced Directives (approved 12-11) failed to indicate that the center would provide, upon request, a copy of the State Advanced Directives brochure to the patient or the patient's representative and failed to indicate that the MR must prominently document whether or not the patient had executed an advance directive. 2. During an interview on 2-10-14 at 1335 hours, staff A1 confirmed that the policy/procedures failed to indicate that a copy of the State Advanced Directives would be provided to the patient upon request and failed to indicate the MR documentation requirement. 	O000224	<p>On 2/26/14 the Facility Administrator revised the Advanced Directives Policy to state the following: If the patient has an Advance Directive, a copy of the Advance Directive will be attached to her patient medical record on the Medical History. If the patient does not have an Advance Directive, upon the request of patient the Center will provide a copy of the State Advanced Directive brochure to the patient or patient's representative. These revisions/additions to the policy will be reviewed by the Medical Staff on 4/15/14 and the Governing Body on 4/18/14. The staff will be trained on this policy once it has been approved during their April staff meeting. The Director of Nursing will be responsible for ensuring this training is completed.</p>	04/18/2014	

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Q000226	<p>416.50(d)(1), (2), & (3) GRIEVANCES - MISTREATMENT, ABUSE The following criteria must be met:</p> <p>(1) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.</p> <p>(2) All allegations must be immediately reported to a person in authority in the ASC.</p> <p>Only substantiated allegations must be reported to the State authority or the local authority, or both.</p> <p>Based on document review and interview, the center failed to ensure that all allegations of abuse, neglect, or mistreatment will be fully documented, immediately reported to a person in authority, and reported to the State and/or local authority if substantiated.</p> <p>Findings:</p> <p>1. The policy/procedure Grievance Submission and Investigation (approved 1-12) failed to indicate that allegations involving verbal, mental, sexual, or physical abuse, mistreatment or neglect will be fully documented, immediately reported to a person in authority, and substantiated allegations must be reported to a State authority and/or local authority.</p>	O000226	<p>On 2/26/14 the Facility Administrator revised the Grievance Policy to include the following: "All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented. All allegations must be immediately reported to a person of authority in the ASC. Only substantiated allegations must be reported to the State authority or the local authority, or both." These revisions/additions to the policy will be reviewed by the Compliance Officer by 3/14/14 and will be reviewed by the Medical Staff on 4/15/14 and the Governing Body on 4/18/14. The staff will be trained on this policy once it has been approved during their April staff meeting. The Director of Nursing will be</p>	04/18/2014

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Q000227	<p>2. During an interview on 2-10-14 at 1335 hours, staff A1 confirmed that the policy/procedure lacked the required elements.</p> <p>416.50(e)(1)(i) RESPECT - PROPERTY & PERSON The patient has the right to the following:</p> <p>(i) Be free from any act of discrimination or reprisal.</p> <p>Based on document review and interview, the policy/procedure and patient rights notice failed to ensure that a patient or their representative may exercise their rights without fear of reprisal.</p> <p>Findings:</p> <p>1. The policy/procedure Patient Rights (approved 1-12) and Patient Rights and Responsibilities notice failed to indicate that a patient may exercise their rights without being subjected to discrimination or reprisal.</p> <p>2. During an interview on 2-10-14 at 1335 hours, staff A1 confirmed that the policy/procedure and Patient Rights and Responsibilities notice lacked the required element.</p>	O000227	<p>responsible for ensuring this training is completed.</p> <p>On 2/26/14 the Facility Administrator revised the notice and policy on patient rights and responsibilities to include the following: "Be free from any act of discrimination or reprisal." These revisions will be reviewed by the Compliance Officer by 3/14/14 and will be reviewed by the Medical Staff on 4/15/14 and the Governing Body on 4/18/14. The staff will be trained on this policy once it has been approved during their April staff meeting. The Director of Nursing will be responsible for ensuring this training is completed.</p>	04/18/2014
Q000228	<p>416.50(e)(1)(ii)</p>			

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Q000233	<p>EXERCISE OF RIGHTS - GRIEVANCES [(1) The patient has the right to the following:]</p> <p>(ii) Voice grievances regarding treatment or care that is (or fails to be) provided. Based on document review and interview, the center policy/procedure and notice of patient rights failed to assure that a patient or their representative may voice grievances regarding treatment or care they receive (or fail to receive).</p> <p>Findings:</p> <p>1. The policy/procedure Patient Rights and Responsibilities (approved 1-12) and Patient Rights and Responsibilities notice failed to indicate that a patient may voice grievances regarding treatment or care that is (or fails to be) provided.</p> <p>2. During an interview on 2-10-14 at 1335 hours, staff A1 confirmed that the policy/procedure and Patient Rights and Responsibilities notice lacked the required elements.</p> <p>416.50(f)(3) SAFETY - ABUSE/HARASSMENT [The patient has the right to -] (3) Be free from all forms of abuse or harassment Based on document review and</p>	0000228	<p>On 2/26/14 the Facility Administrator revised the notice and policy on patient rights and responsibilities to include the following: "Voice grievances regarding treatment or care that is (or fails to be) provided." These revisions will be reviewed by the Compliance Officer by 3/14/14 and will be reviewed by the Medical Staff on 4/15/14 and the Governing Body on 4/18/14. The updated posting will be posted on 4/21/14.</p>	04/21/2014
		0000233	<p>On 2/26/14 the Facility Administrator revised the notice</p>	04/21/2014

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Q000241	<p>interview, the center policy/procedure and notice of patient rights failed to assure the patient right to be free from all forms of abuse or harassment.</p> <p>Findings:</p> <ol style="list-style-type: none"> The policy/procedure Patient Rights and Responsibilities (approved 1-12) and Patient Rights and Responsibilities notice failed to indicate the patient right to be free from all forms of abuse or harassment. During an interview on 2-10-14 at 1335 hours, staff A1 confirmed that the policy/procedure and Patient Rights and Responsibilities notice lacked the required elements. <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 staff interview, the infection control committee failed to ensure that an active, effective, infection control plan was in place in failing to adopt the contracted housekeeping company cleaning process, and products used, for terminal cleaning of the surgery center; and failed to ensure</p>	0000241	<p>and policy on patient rights and responsibilities to include the following: "Be free from all forms of abuse or harassment." These revisions will be reviewed by the Compliance Officer by 3/14/14 and will be reviewed by the Medical Staff on 4/15/14 and the Governing Body on 4/18/14. The updated posting will be posted on 4/21/14. The staff will be trained on this policy once it has been approved during their April staff meeting. The Director of Nursing will be responsible for ensuring this training is completed.</p> <p>A meeting with the contracted services company for housekeeping has been scheduled for 3/17/14 to review cleaning policies and procedures. These policies and procedures will be presented to the QAP&I and Medical Staff on April 15, 2014 if approved they will then be presented to the governing body on April 18, 2014.</p>	04/06/2014			

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	<p>complete disinfection of the floor of the sterilization room, as per standards of practice.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. review of the QA & I (quality assurance and improvement) meeting minutes for 2013 (1/17/13, 4/25/13, 7/1/13, and 10/17/13) indicated there was no documentation of the approval of the cleaning processes and products utilized in terminally cleaning the surgery center by the contracted cleaning company 2. interview at 12:20 PM on 2/11/14 with staff member #62, the administrator, indicated: <ol style="list-style-type: none"> a. the QA & I committee acts as the infection control committee for the facility b. documentation that the infection control committee approved the contracted housekeeping company's cleaning process and cleaning products cannot be produced c. it is assumed that the approval was done "years ago" 3. at 3:15 PM on 2/11/14 while on tour of the surgery area in the company of staff member #60, the infection control practitioner, it was observed in the sterilization room that an area of the flooring, approximately 2 1/2 feet by 2 		<p>The Facility Administrator will be responsible for ensuring the action and outcome is documented. The property manager was notified on 2/24/14 of the floor repair that needs to be done. He has contacted a vendor to repair the floor and a quote will be submitted by 3/14/14. Repair work will be completed by 4/6/14. The Facility Administrator will be responsible to ensure this work has been completed by said date.</p>	

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S000000	<p>1/2 feet square, was covered with strips of gray duct tape</p> <p>4. interview with staff member #60 at 3:15 PM on 2/11/14 indicated:</p> <p>a. a large, floor model, autoclave/sterilizer used to sit on that area of flooring, but has been replaced by a counter top model</p> <p>b. the hole in the floor from the previous autoclave is covered by duct tape and does not allow for appropriate disinfection of the floor in this restricted area of the facility</p> <p>Based on document review and interview, the infection control committee</p> <p>The visit was for a licensure survey.</p> <p>Facility Number: 003375</p> <p>Survey Date: 2-10-14 to 2-11-14</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN</p>	S000000		

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S000146	<p>Public Health Nurse Surveyor</p> <p>QA: claughlin 02/17/14</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c) (3)</p> <p>(c) The governing body shall do the following:</p> <p>(3) Require the chief executive officer or a designee to attend meetings of the governing body and its committees and act as its representative at medical staff meetings.</p> <p>Based on document review and interview, the governing board failed to ensure that the chief executive officer (CEO) acted as its (governing board) representative at medical staff meetings.</p> <p>Findings:</p> <p>1. Center documentation indicated that MD11 was the center CEO and a governing board member.</p> <p>2. Medical Staff minutes dated 1-17-13, 4-25-13, 7-01-13, 10-17-13 and 1-16-14 indicated that MD11 failed to attend any</p>	S000146	The Facility Administrator will be responsible for scheduling the medical staff meetings quarterly and will ensure that the CEO or his designee will be in attendance. The next meeting is scheduled for April 15, 2014.	04/15/2014

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S000320	<p>medical staff meetings.</p> <p>3. During an interview on 2-11-14 at 1220 hours, the administrator A1 confirmed that MD11 failed to attend the last 5 quarterly medical staff meetings.</p> <p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(2)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(2) All functions, including, but not limited to, the following:</p> <p>(A) Discharge and transfer. (B) Infection control. (C) Medication errors. (D) Response to patient emergencies.</p> <p>Based on document review and interview, the center failed to ensure that the required functions of discharge and transfer and response to patient emergencies were evaluated by the quality assessment and improvement (QA&I) program.</p> <p>Findings:</p> <p>1. QA&I committee minutes dated 1-17-13, 4-25-13, 7-01-13, 10-17-13 and</p>	S000320	<p>The Facility Administrator added discharges, transfers, medication errors and response to patient emergencies to the QAP&I template and will be reported during the quarterly meeting. The Facility Administrator met with the DON on 2/19/14 and the DON will be responsible for ensuring that these cases are</p>	02/19/2014

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S000328	<p>1-16-14 failed to indicate evidence that patient discharges were evaluated and reviewed by the QA&I program.</p> <p>2. During an interview on 12-19-12 at 1610 hours, staff A1 confirmed that the discharge function had not been evaluated through the QA&I program.</p> <p>3. Center documentation indicated one patient transfer in 2013 and the QA&I committee minutes failed to indicate that the patient transfer / emergency response was evaluated and reviewed.</p> <p>4. During an interview on 2-11-14 at 1415 hours, administrator A1 confirmed that QA&I program failed to document an evaluation and review of the 2013 patient transfer.</p> <p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(b)</p> <p>(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:</p> <p>(1) The action must be documented. (2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on</p>		<p>peer reviewed so that actions and outcomes are implemented if necessary. The Facility Administrator will ensure ongoing compliance.</p>				

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	<p>patient care.</p> <p>Based on document review and interview, the center failed to document an action in response to opportunities for improvement found through the quality assessment and improvement (QA&I) program.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. QA&I committee minutes dated 4-25-13 and 7-01-13 indicated that the medical record (MR) service conducted quarterly MR reviews on 2-20-13 and 5-22-13 and reported the following findings on both visits: "...operative notes were not transcribed in a timely fashion. Facility needs to determine the reason for the extended length of time. Reports should not take any more than 24-48 hours to transcribe ..." The QA&I minutes dated 4-25-13, 7-01-13, and 10-17-13 failed to indicate a committee action in response to the transcription delays reported by the MR reviewer. 2. The QA&I meeting minutes dated 10-17-13 and 1-16-14 failed to indicate that the MR service conducted MR reviews on 8-29-13 and 11-26-13 or report of the findings and failed to indicate a committee action or discussion of the results of ongoing monitoring in response to any identified concerns. 	S000328	<p>During the quarterly QAP&I meeting all issues and/or concerns from the previous meeting will be discussed and reviewed. Any action discussed will be documented as well as the outcome. If the action was not implemented the item will be discussed and placed on the agenda for the next meeting with a new action documented. The Facility Administrator will be responsible for ensuring compliance.</p>	02/26/2014	

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S000404	<p>3. Center documentation indicated one patient transfer in 2013 prior to July and the 7-01-13 QA&I committee minutes failed to indicate that the patient transfer / emergency response was evaluated and failed to indicate a committee action or recommendation for improvement in response to the patient transfer.</p> <p>4. During an interview on 2-11-14 at 1415 hours, administrator A1 confirmed that QA&I program failed to document an evaluation and action in response of the 2013 patient transfer.</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 committee failed to ensure that an active, effective, infection control plan was in place in failing to adopt the contracted housekeeping company cleaning process,</p>	S000404	A meeting with the contracted services company for housekeeping has been scheduled for 3/17/14 to review cleaning policies and procedures. These policies and procedures will be presented to	04/18/2014

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S000428	<p>and products used, for terminal cleaning of the surgery center.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. review of the QA & I (quality assurance and improvement) meeting minutes for 2013 (1/17/13, 4/25/13, 7/1/13, and 10/17/13) indicated there was no documentation of the approval of the cleaning processes and products utilized in terminally cleaning the surgery center by the contracted cleaning company 2. interview at 12:20 PM on 2/11/14 with staff member #62, the administrator, indicated: <ol style="list-style-type: none"> a. the QA & I committee acts as the infection control committee for the facility b. documentation that the infection control committee approved the contracted housekeeping company's cleaning process and cleaning products cannot be produced c. it is assumed that the approval was done "years ago" <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>the QAP&I and Medical Staff on April 15, 2014 if approved they will then be presented to the governing body on April 18,2014. The Facility Administrator will be responsible for ensuring the action and outcome is documented.</p>	

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S000466	<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 observation and staff interview, the infection control committee failed to ensure complete disinfection of the floor of the sterilization room.</p> <p>Findings:</p> <ol style="list-style-type: none"> at 3:15 PM on 2/11/14 while on tour of the surgery area in the company of staff member #60, the infection control practitioner, it was observed in the sterilization room that an area of the flooring, approximately 2 1/2 feet by 2 1/2 feet square, was covered with strips of gray duct tape interview with staff member #60 at 3:15 PM on 2/11/14 indicated: <ol style="list-style-type: none"> a large, floor model, autoclave/sterilizer used to sit on that area of flooring, but has been replaced by a counter top model the hole in the floor from the previous autoclave is covered by duct tape and does not allow for appropriate disinfection of the floor in this restricted area of the facility <p>410 IAC 15-2.5-1</p>	S000428	The property manager was notified on 2/24/14 of the floor repair that needs to be done. He has contacted a vendor to repair the floor and a quote will be submitted by 3/14/14. Repair work will be completed by 4/6/14. The Facility Administrator will be responsible to ensure this work has been completed by said date.	04/06/2014

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	<p>INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(g)(3)</p> <p>Sterilization services must be directed by a qualified person or persons and must provide for the following:</p> <p>(3) Records of results must be maintained and evaluated periodically in accordance with 410 IAC 15-2.4-2 to include, but not limited to, the following:</p> <p>(A) Records of recording thermometers or a daily record of the sterilizing cycle (date, time, temperature, pressure, and contents) for each sterilizer load.</p> <p>(B) Results of biological indicators used in testing the sterilizing processes.</p> <p>Based on document review and interview, the infection control committee failed to ensure the documentation of periodic review of biologicals and sterilizer reports by reporting at the infection control and quality assurance meetings.</p> <p>Findings: 1. review of the facility QA & I (quality assurance and improvement) committee meetings for 2013 (1/17/13, 4/25/13, 7/1/13, and 10/17/13) indicated there was no documentation of evaluation of biologicals and sterilization information</p>	S000466	The results of the biological indicators have been added to the QAP&I template as of 2/26/14 and the Infection Control Officer will be responsible for reporting this to the QAP&I Committee during the April 15, 2014 meeting and all other meetings to follow	02/26/2014

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S000710	<p>2. interview with the infection control practitioner, staff member #60, at 2:20 PM on 2/11/14 indicated:</p> <p>a. the infection control committee is the same as the QA & I committee (infection control processes are handled through this committee)</p> <p>b. there has been no inclusion of biological and sterilization reporting and evaluation at the QA & I meetings</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(a)(4)</p> <p>The medical staff shall do the following:</p> <p>(4) Maintain a reasonably accessible hard copy or electronic file for each member of the medical staff, which includes, but is not limited to, the following:</p> <p>(A) A completed, signed application.</p> <p>(B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.</p> <p>(C) A current copy of the individual's:</p> <p>(i) Indiana license showing date of</p>			

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	<p>licensure and number or available data provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the appropriate licensing board.</p> <p>(ii) Indiana controlled substance registration showing number as applicable.</p> <p>(iii) Drug Enforcement Agency registration showing number as applicable.</p> <p>(iv) Documentation of experience in the practice of medicine.</p> <p>(v) Documentation of specialty board certification as applicable.</p> <p>(vi) Documentation of privilege to perform surgical procedures in a hospital in accordance with IC 16-18-2-14(3)(C).</p> <p>(D) Category of medical staff appointment and delineation of privileges approved.</p> <p>(E) A signed statement to abide by the rules of the center.</p> <p>(F) Documentation of current health status as established by center and medical staff policy and procedure and federal and state requirements.</p> <p>(G) Other items specified by the center and medical staff.</p> <p>Based on document review and</p>	S000710	On 2/24/14 the Facility	03/14/2014

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	<p>interview, the center failed to assure that allied health professionals (AHP) were reappointed in accordance with its medical staff bylaws for 1 allied health professional (AH21) file reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The Medical Staff Bylaws (approved 1-13) indicated the following: " Any individual who desires to obtain AHP privileges in the ASC shall submit an application for employment or an application for privileges, as applicable ... [including] ...the express statement of the applicant that he/she has read, understands, and agrees to abide by the Medical Staff Bylaws and Rules and Regulations ... " 2. Review of the credential file for Certified Registered Nurse Anesthetist (CRNA) staff AH21 failed to indicate a signed statement that the CRNA agreed to abide by the medical staff bylaws, rules and regulations as a condition for granting of privileges by the governing board. 3. During an interview on 2-11-14 at 1620 hours, administrator A1 confirmed that the credential file lacked the required documentation. 		<p>Administrator sent the Medical Staff Bylaws, rules and regulations to all CRNA's that are credentialed in the center. A signed acknowledgement will be placed in their files by 3/14/14. The Facility Administrator will be responsible to ensure this has been completed by 3/14/14.</p>				

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S000736	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(B)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(B) Meeting requirements of the medical staff to include, at a minimum, the following:</p> <p>(i) Frequency, at least quarterly. (ii) Attendance.</p> <p>Based upon document review, the medical staff failed to establish attendance requirements for its quarterly medical staff meetings to assure that the meetings were held with the required attendance.</p> <p>Findings:</p> <p>1. Review of the Medical Staff Bylaws, Rules and Regulations (approved 1-13) failed to indicate the minimum attendance (quorum) requirements for the medical staff to meet and conduct its business and failed to indicate a requirement for the center chief executive officer (CEO) to attend the medical staff meetings as the governing body representative in accordance with State law 410 IAC 16-21(c)(3).</p>	S000736	The Facility Administrator will be responsible for updating the Medical Staff Bylaws by 3/14/14 to include a minimum attendance of 2 MDs and the CEO/and or designee to assure that the meetings are held with the required attendance to conduct its business. This revision will be reviewed by the Medical Staff on 4/15/14 and if approved will be sent to the Governing Body for their review and approval on 4/18/14. The Facility Administrator will be responsible for ensuring this is completed and approved by 4/18/14.	04/18/2014

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S001026	<p>2. Center documentation indicated that the center CEO was MD11.</p> <p>3. The medical staff meeting minutes dated 1-17-13, 4-25-13, 7-01-13, 10-17-13 and 1-16-14 failed to indicate that the CEO attended the last five medical staff meetings and the meeting minutes dated 10-17-13 indicated that only two medical staff (MD15 and MD17) attended the meeting. Therefore, it could not be determined that the medical staff meetings were held with the required attendance.</p> <p>4. During an interview on 2-11-14 at 1020 hours, staff A1 the administrator A1 confirmed that only MD15 and MD17 attended the 10-17-13 medical staff meeting.</p> <p>5. During an interview on 2-11-14 at 1220 hours, staff A1 the administrator A1 confirmed that MD11 failed to attend the last 5 quarterly medical staff meetings.</p> <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(E)(i)</p> <p>Pharmaceutical services must have the following:</p> <p>(3) Written policies and procedures</p>			

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	<p>developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(E) Drugs must be accurately and clearly labeled and stored in specially-designated, well-illuminated cabinets, closets, or storerooms and the following:</p> <p>(i) Drug cabinets must be accessible only to authorized personnel.</p> <p>Based on policy and procedure review, observation, and staff interview, the facility failed to ensure that medications were not accessible to unauthorized personnel.</p> <p>Findings:</p> <p>1. review of the policy and procedure "Quality Management/Inspection of Drug/Medication Storage Area", no policy number and no date of last review or revision, indicated:</p> <p>a. under "Procedure", in item 3., it reads: "All drugs are stored in accordance with the current established standards..."</p> <p>b. the accessibility of medications to unauthorized personnel is not addressed within the policy</p> <p>2. at 3:25 PM on 2/11/14, while on tour of the nursing area of the pre/post op section of the surgery center, in the</p>	S001026	<p>On 2/24/14 a refrigerator lock kit was ordered to</p> <p>ensure that medications were not accessible to unauthorized personnel. This lock will be placed on the refrigerator</p> <p>by 3/14/14. The Facility Administrator</p> <p>will be responsible for ensuring this has been installed. The medication nurse/or designee will be responsible for unlocking and locking this during the surgical day. The keys will be kept in the Director of Nursing's office at the end of each surgery day to prohibited unauthorized access.</p>	03/14/2014

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S001146	<p>company of staff member #60, the infection control practitioner, it was observed that a large refrigerator containing: multi dose solutions of eye drops; one vial of 500 mg Vancomycin; and one vial of 1 GM penicillin, lacked any capability of being locked and inaccessible to the after hours contracted housekeeping personnel</p> <p>3. interview with staff members #60, the infection control practitioner, and #62, the facility administrator, at 4:40 PM on 2/11/14 indicated the policy (listed in 1. above):</p> <p>a. does not address maintaining a condition of inaccessibility of medications for unauthorized personnel</p> <p>b. the standard of practice is to have all medications locked and inaccessible</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 maintained which may result in a hazard to patients, public, or</p>			

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	<p>employees. Based on document review, policy and procedure review, observation, and staff interview, the facility failed to ensure that no condition was created that might result in a hazard to patients, visitors, or staff.</p> <p>Findings: 2. review of the policy and procedure "Blanket and Solution -Warming Cabinet Temperature", no policy number, not dated with a last date reviewed/ revised, indicated warming temperature was the only item addressed in the policy, cleanliness of the unit was not addressed</p> <p>3. at 3:35 PM on 2/11/14, while on tour of the pre/post op area of the facility (just outside bay #4) in the company of staff member #60, the infection control practitioner, it was observed that the Getinge blanket warmer had an accumulation of dust on the lowest shelf of the lower cabinet</p> <p>4. interview with staff member #60 at 3:35 PM on 2/11/14 indicated: a. staff member #60 is the staff member who cleans the unit monthly b. the monthly temperature log indicates the warming cabinet was last cleaned on 1/27/14 c. the facility has changed the type of blankets being warmed to hopefully have</p>	S001146	<p>On 2/26/14 the policy and procedure "Blanket and Solution – Warming Cabinet Temperature", the Facility Administrator add #7 that says that the "Blanket Warmer will be cleaned per manufacturer guidelines. Cleaning of the unit has also been added to the daily checklist for the staff to clean every surgery day. The Infection Control Officer will be responsible for ensuring the cleanliness of the unit.</p> <p>On Page 17 in regards to the refrigerator the Facility Administrator revised #2 to say "Nursing staff is responsible for maintaining the refrigerators and clean them weekly."</p> <p>The Facility Administrator updated the policy and procedure "Surgical Guidelines for Safe Patient Care" to include the following:</p>	04/18/2014

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	<p>less dust/lint produced within the unit</p> <p>d. the blanket warmer may need to be cleaned more frequently than once/month</p> <p>5. review of the policy and procedure "Universal/Standard Precautions Practices", no policy number and no date of last review or revision, indicated:</p> <p>a. on page 17, in section "V. Refrigerator Temperature, Patient", it was indicated that temperatures of patient and staff refrigerators are to be logged, but lacked any indication of when, how often, or by whom, the refrigerators will be cleaned</p> <p>6. at 11:35 AM on 2/10/14, it was observed in the staff break room that the staff refrigerator:</p> <p>a. had a large amount of spilled liquid pooled and dried on the lowest shelf of the freezer</p> <p>b. had a brown liquid that had spilled and dried in the ice shoot of the freezer door</p> <p>c. had crumbs/debris under the vegetable drawer of the refrigerator</p> <p>d. had dried liquids, crumbs, and debris on the shelf units of the refrigerator door</p> <p>7. interview with staff member #62, the facility administrator, at 11:35 AM on 2/10/14 indicated:</p> <p>a. it was agreed that the staff</p>		<p>"Pregnancy Testing – The surgeon may order a pregnancy test for any woman of</p> <p>childbearing age (menstruating age) unless they have had a documented</p> <p>hysterectomy or tubal ligation. The</p> <p>patient may refuse this testing however; this must be documented in the medical</p> <p>record. The acceptance and refusal of a pregnancy test has been added to the medical history form to be documented by the nursing staff. Should the patient elect to</p> <p>receive the testing % of accuracy will be discussed with the patient as well as</p> <p>risks and benefits of IV medication and will be documented in the medical record.</p> <p>These revisions/additions to the policy will be</p> <p>reviewed by the Medical Staff on 4/15/14 and the Governing Body on 4/18/14. The staff will be trained on this policy once</p>	

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S001180	<p>refrigerator/freezer was dirty as listed in 6. above</p> <p>b. there is currently no routine scheduled cleaning process for the facility refrigerators</p> <p>8. review of patient medical records indicated that pt. #10 was a 25 year old female who had surgery on 11/14/13 and:</p> <p>a. listed their most recent menstrual cycle as 8/30/13</p> <p>b. lacked any indication that a pregnancy test was done prior to surgery</p> <p>9. interview with staff member #62, the facility administrator, at 2:20 PM on 2/11/14 indicated:</p> <p>a. the facility does not have a policy related to pregnancy tests, who should have them, when they are required, etc.</p> <p>b. it is a facility process that any female patient of "childbearing years" should have a physician ordered pregnancy test prior to surgery</p> <p>c. pt. #10 should have had a pregnancy test ordered prior to their surgery date of 11/14/13</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(1)</p>		<p>it has been approved during the next staff meeting. The Director of Nursing will be responsible</p> <p>for ensuring this training is completed.</p>		

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	<p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(1) A review of safety functions by a committee appointed by the chief executive officer that includes representatives from administration and patient care services.</p> <p>Based on document review and interview, the center failed to develop and maintain a safety management program that included a review of safety functions by a committee appointed by the chief executive officer and included representatives from administration and patient care services.</p> <p>Findings:</p> <p>1. The Medical Staff Bylaws (approved 1-13) indicated the following: " ...Committees of the Medical Staff: QA&I Committee ...shall consist of the chief executive officer (CEO), the Medical Director or his/her designee ... (and) ...the Director of Anesthesia11.2-2 The QA&I committee shall11.2-2.13 Incorporate the functions of a Safety Committee ... " The medical staff bylaws failed to assure that the safety committee membership included representatives from administration and patient care services.</p>	S001180	<p>A revision was made to the Medical Staff Bylaws by the Facility Administrator on 2/26/14. "11.2-2.13 Incorporate the functions of a Safety Committee. The functions shall include, but not be limited to: Assurance that the Safety Committee will have a representative from administration and patient care services." Page #5 under section 16.0 Safety states the following: Formation of Safety Committee: The committee will consist of the Safety Officer, clinic staff team leaders or designees to monitor and guide the Safety Program of the center. The committee will meet at least quarterly to maintain an active, ongoing safety program. The committee will meet to identify and prevent safety issues including physical safety, patient and staff safety, incident reporting, Allen County Emergency Preparedness, fire safety, and update the program with current OSHA guidelines. The Facility Administrator is responsible for monitoring safety within the Center. The Facility Administrator will utilize the</p>	04/18/2014

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S001182	<p>2. Review of the policy/procedure table of contents (approved 1-14) failed to indicate a policy/procedure titled Safety Committee within the section 16.0 for Safety.</p> <p>3. During an interview on 2-10-14 at 1115 hours, administrator A1 indicated that they (A1) were the Safety Officer.</p> <p>4. QA&I committee minutes dated 1-17-13, 4-25-13, 7-01-13 and 10-17-13 lacked evidence of safety committee member participation including a representative from patient care services within the Safety and Environment section of the minutes.</p> <p>5. During an interview on 2-11-14 at 1320 hours, administrator A1 confirmed that the medical staff bylaws failed to assure participation by a representative from patient care services if the meeting was incorporated within the medical staff/QA&I committee functions.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(2)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p>		<p>expertise of other Center personnel and entities providing contractual services to equipment of the Center as needed to maintain a safe environment within the Center. The Governing Body will appoint the Facility Administrator or other qualified individual. The Facility Administrator will appoint a safety committee which includes representatives from administration and patient care services. The Facility Administrator will ensure that a member of patient services and administration be in attendance at these meetings during the first quarter and ongoing. These revisions/additions to the policy will be reviewed by the Medical Staff on 4/15/14 and the Governing Body on 4/18/14.</p>				

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	<p>(2) An ongoing center-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.</p> <p>Based on document review and interview, the center failed to develop and maintain an ongoing, center-wide process for assessing and evaluating hazards and safety practices by the safety committee.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. The Safety committee portion of the QA&I meeting minutes dated 7-01-13 failed to indicate that a disaster drill conducted 5-23-13 was discussed and reviewed by the safety committee. No documentation indicated any committee recommendations or after action report findings to improve center safety. 2. The Safety committee portion of the QA&I meeting minutes dated 7-01-13, 10-17,13 and 1-16-14 failed to document and report results of the center staff participation on 6-27-13 and 10-30-13 with District 3 ASC disaster management meetings reported by administrator A1. 3. The Safety committee portion of the QA&I meeting minutes dated 4-25-13, and 7-01-13 failed to indicate center fire drills were conducted on 3-15-13 and 6-10-13. The Safety committee portion of 	S001182	Disaster Drills and Fire Drills have been added to the QAP&I template as of 2/26/14 to ensure that discussions, actions, outcomes are documented and implemented to ensure and improve center safety. The Facility Administrator and/or acting secretary will be responsible for recording this during the meetings.	02/26/2014

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	<p>the QA&I meeting minutes dated 10-17-13 and 1-16-14 failed to indicate center fire drills were conducted on 9-16-13 and 12-20-13 and lacked documentation of any committee discussion with recommendations or actions to improve center safety.</p> <p>4. During an interview on 2-11-14 at 1330 hours, administrator A1 confirmed that the safety committee minutes failed to indicate that the committee reviewed and discussed the indicated activities and confirmed that the minutes lacked evidence of committee recommendations or actions to improve center safety.</p>				