

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  15C0001095	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  10/01/2014
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NAME OF PROVIDER OR SUPPLIER  KLEINERT KUTZ SURGERY CENTER IN AFFILIATION W/ FLO	STREET ADDRESS, CITY, STATE, ZIP CODE 3605 NORTHGATE CT, STE 101 NEW ALBANY, IN 47150
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S000000	This visit was for a standard licensure survey.  Facility # 002524  Survey Dates: 9/29/14 to 10/1/14  Surveyor: Trisha Goodwin, RN BS Public Health Nurse Surveyor  QA: clauglin 10/22/14	S000000		
S000048	410 IAC 15-2.3-1 ISSUANCE OF LICENSE 410 IAC 15-2.3-1 (d)  (d) All changes in ownership, name, and address must be reported in writing to the division. Reapplication must be filed when a change of fifty percent (50%) or greater ownership occurs. Based on interview, the facility failed to notify in writing to the division a change in ownership in one instance.  Findings:  1. In interview on 10/1/14 at 4:25pm, the administrator, A2, indicated, on the document provided as the medical staff	S000048	1 A letter will be sent to the ISDH regarding changing ownership within Kleinert Kutz related to the ASC 2 A letter will be sent whenever this changes again 3 Administrator 4 11-21-14	11/21/2014

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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S000122	<p>(MS) listing, nine (9) medical staff members who have financial interest in the center. A2 further indicated one of the owners was added in 2014. Review of facility written notification to the division was requested at that time and A2 indicated the division had not been notified and he/she was unaware of the need to notify. No further documentation was provided prior to exit.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (b)(3)</p> <p>The governing body shall do the following:</p> <p>(3) Ensure that the medical staff has approved bylaws and rules, and that the bylaws and rules are reviewed and approved at least triennially by the governing body.</p> <p>Based on document review and interview, the governing body (GB) failed to ensure that the medical staff (MS) reviewed and approved rules within the past three (3) years.</p> <p>Findings:</p> <p>1. Review of the document titled Medical Staff Rules indicated a review and approval date of 5/14/2009.</p> <p>2. Review of MS meeting minutes dated</p>	S000122	<p>1 This was included in the Medical Staff meeting on 11-3-14 and will be addressed at the November 20, 2014, BofD meeting</p> <p>2 When the review of the Medical Staff Bylaws and Rules comes due again, the Rules will be documented as reviewed as well</p> <p>3 Administrator</p> <p>4 11-21-14</p>	11/21/2014			

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S000172	<p>7/22/13, 1/27/14, 4/21/14 and 7/28/14 lacked evidence of MS rules review or approval.</p> <p>3. Review of GB meeting minutes dated 10/21/13, 2/20/14, 5/15/14 and 8/21/14 lacked evidence of review or approval of MS rules.</p> <p>4. In interview on 10/1/14 at 4:30pm, administrator A2 indicated the MS rules were included in the bylaws and were approved in 2013.</p> <p>5. Review of the document indicated to be GB meeting minutes dated April 25, 2013 indicated, under the heading of Medical Staff Bylaws: The bylaws were reviewed and approval of this update was accomplished unanimously. The document lacked evidence of MS Rules review or approval. No further documentation was provided prior to exit.</p> <p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (L)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(L) Maintaining personnel records for each employee of the center which include personal data, education and experience, evidence of participation</p>			

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	<p>in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-rays, as applicable.</p> <p>Based on document review and interview, the facility failed to maintain personnel records for each employee of the center in two (2) instances.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the employee list provided indicated 26 employees which did not included the administrator A2. From this list six (6) files were selected at random for review. Review of the personnel file for A2 was added to the list.</li> <li>2. In interview on 9/29/14 at 10:30am, administrator A2 indicated personnel files were not kept for two (2) of the employees selected. A2 indicated these employees to be exempt from needing a file because they were considered staff of the associates. A2 further indicated the employees were paid by the center and were not under contract.</li> <li>3. In interview on 10/1/14 at 4:00pm, administrator A2 confirmed the above and nothing more was provided prior to exit.</li> </ol>	S000172	<ol style="list-style-type: none"> <li>1 Files have been created for the two employees Health records are being compiled These will be kept in the file with all other employees of the surgery center</li> <li>2 Files will be maintained for all employees documented as part of the surgery center staff</li> <li>3 Administrator</li> <li>4 11-21-14</li> </ol>	11/21/2014			

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S000176	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (M)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-service in special procedures.</p> <p>Based on document review and interview, the Governing Body (GB) failed to ensure personnel demonstration and documentation of personnel competency related to assigned responsibilities in 3/3 instances (P4, P6 and P7).</p> <p>Findings:</p> <p>1. Review of personnel files for registered nurses P4, P6 and P7 lacked documentation of annual performance based competencies in the areas of intravenous and medication administration.</p> <p>2. In interview on 10/1/14 at 3:30pm, RN and Manager of Operations employee A1 confirmed the facility did not conduct competency evaluations of the above clinical skills.</p>	S000176	<p>1, IV and Medication Administration competencies are being developed and will be done by appropriate staff members</p> <p>2 This will be done on an annual basis</p> <p>3 Manager of Operations and Administrator</p> <p>4 11-21-14</p>	11/21/2014

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S000320	<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 Governing Body (GB) failed to ensure a center-wide quality assessment and improvement program (QAPI) for four (4) functions of the facility within the past four (4) quarters.</p> <p>Findings:</p> <p>1. Review of QAPI meeting minutes dated 3rd quarter 2013, 4th quarter 2013, 1st quarter 2014 and the document titled CQI Report 2nd Quarter 2014 failed to include the functions of transcription, discharge, response to patient emergencies and reportable events. 2. Review of the document titled Quality Assessment and Performance</p>	S000320	<p>1 Transcription, Discharge, Response to Patient Emergency, and Reportable Events has been added to the CQI report and committee meeting agenda each quarter This included discussion of each at the Medical Staff meeting on 11-3-14 2 These topics will be included on the agenda and discussion for each CQI, Medical Staff, and Governing Board for each quarter 3 Administrator 4 11-21-14</p>	11/21/2014			

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S000400	<p>Improvement Plan under the subtitle Scope of CQI Process it indicated: The QAPI process is a comprehensive program in which all areas, services and functions participate.</p> <p>3. In interview on 10/1/14 at 4:00pm, administrator A2 indicated all aspects of the facility were monitored, just don't show in QAPI. No further documentation was provided prior to exit.</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 document review, the center failed to follow policy and procedure and minimize infection exposure in two (2) instances.</p> <p>Findings:</p> <p>1. During patient tracer observation on 9/30/14 at 1:50pm in the operating room, the CRNA (certified registered nurse anesthetist) AH3 was observed injecting into the IV (intravenous) medication port</p>	S000400	<p>1 Policies regarding this have been reviewed with the CRNA's by the Manager of Operations These have also been reviewed and shared among the group of independent CRNA practitioners</p> <p>2 CRNA's will be reminded often to follow policy Observation will be done to ensure compliance</p> <p>3 Manager of Operations 4 11-21-14</p>	11/21/2014

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S000732	<p>without first cleansing.</p> <p>2. During patient tracer observation on 9/30/14 at 1:50pm in the operating room, AH3 was observed dabbing the rubber injection port of an open medication vial prior to needle access with a small gauze pad lying open on the anesthesia cart.</p> <p>3. Review of facility P&amp;P Subject: Medication Administration, indicated in the section subtitled Administration: 20. If a medication vial has already been opened, the rubber septum should be disinfected with alcohol prior to piercing it. The same P&amp;P, same section, number 24 indicated: If a medication is to be administered through an IV tubing, the port (rubber or safety) is to be cleaned with alcohol sponge before administering the medication.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(2)</p> <p>These bylaws and rules must be as follows:</p> <p>(2) Be reviewed at least triennially. Based on document review and interview, the Center's Medical Staff (MS) failed to review MS rules triennially.</p>	S000732	1 Medical Staff Rules are included with the Medical Staff Bylaws, however, since they were not documented as reviewed in 2013, the Rules were reviewed at the Medical Staff	11/21/2014

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S001010	<p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the document titled Medical Staff Rules indicated the most recent review and approval as 5/14/2009.</li> <li>2. Review of MS meeting minutes dated 7/22/13, 1/27/14, 4/21/14 &amp; 7/28/14 lacked documentation of MS rules review.</li> <li>3. Review of the document indicated to be Governing Body (GB) meeting minutes dated April 25, 2013 indicated, under the heading of Medical Staff Bylaws: The bylaws were reviewed and approval of this update was accomplished unanimously. The document lacked evidence of MS Rules review or approval. No further documentation was provided prior to exit.</li> <li>4. In interview on 10/1/14 at 4:30pm, administrator A2 indicated the MS rules were included in the bylaws and were approved in 2013.</li> </ol> <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 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,</p>		<p>meeting on 11-3-14 and will go to the Governing Board on 11-20-14</p> <ol style="list-style-type: none"> <li>2 Documentation of Medical Staff Rules will be included in the future reviews and dated in both the Medical Staff meeting and Governing Board meetings</li> <li>3 Admiinistrator</li> <li>4 11-21-14</li> </ol>	

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	<p>including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on document review, observation, and interview, the center failed to label drugs according to policy and procedure (P&amp;P) in one (1) instance.</p> <p>Findings:</p> <p>1. Review of the P&amp;P Subject: Medication Administration, last reviewed 8/14, in the section subtitled Administration #13 indicated: All multidose medications vials must be dated and initialed when opened by the individual initially using the vial. Vials are discarded after 28 days.</p> <p>2. Review of the P&amp;P Subject: Medication Control and Accountability, last reviewed 8/14, in the section subtitled Outdated, Discontinued, Deteriorated &amp; Recalled Drugs: #3 indicated: ...outdated drugs are disposed of or are returned to the purchasing agent.</p> <p>3. During tour of the facility on 9/29/14 at 10:45am, in the presence of A1, Operations Manager, in the narcotic drawer an opened bottle of Midazolam syrup 2mg/ml containing approximately 65ml dated 8/28/14 without initials was noted.</p> <p>2. In interview on 9/29/14 at 10:45am,</p>	S001010	<p>1 The medication will be dated and initialed as required This was started immediately after the survey Individual doses are also being explored</p> <p>2 Dating and initialing of medication will be done consistently</p> <p>3 Manager of Operations</p> <p>4 10-2-14</p>	10/02/2014			

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S001012	<p>A1 indicated the above to be improperly labeled and expired. A1 indicated P&amp;P is for opened medications to be labeled with date, time and initials and to expire 28 days after opening.</p> <p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(B)</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>(B) Drug administration according to established center policies and acceptable standards of practice. Based on medical record review, document review and interview, the center failed to administer medications according to policy and procedure (P&amp;P) and acceptable standards of practice in 9 (Pt #7, Pt #8, Pt #9, Pt #15, Pt #16, Pt #18, Pt #26, Pt #27, Pt #30) of 28 instances.</p> <p>Findings:</p> <p>1. Review of 28 medical records (MR) indicated the following:</p>	S001012	<p>1 Policies and procedures were reviewed with nursing staff at a staff meeting on 11-6-14</p> <p>2 Chart Review and random check of documentation with discussion at nursing staff meetings for compliance</p> <p>3 Manager of Operations</p> <p>4 11-21-14</p>	11/21/2014

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	<p>a. Pt #7 standing order indicated 60 ml Sensorcaine 0.5% pl intra-op, 40 ml was noted as dosage on medication administration record (MAR)</p> <p>b. Pt #8 standing order indicated Versed 4 mg and Fentanyl 50 mcg IV (intravenous) pre-op, the MAR indicated 4 mg Midazolam given via route of irrigation and 50 mcg Fentanyl administered as irrigation.</p> <p>c. Pt #9 standing order indicated Marcaine 30 ml intra-op, the MAR indicated 60 ml administered.</p> <p>d. Pt #15 MAR indicated triple antibiotic Ointment 0.9 administered topical, the standing order did not indicated antibiotic ointment was ordered.</p> <p>e. Pt #16 standing order indicated Fentanyl 100 mcg IV, the MAR indicated 50 mcg given IV.</p> <p>f. Pt #18 standing order, signed as noted/RN on 5/13/14 at 0855, indicated EKG pre-op and Marcaine 0.25% pl, dosage not indicated, intra-op, the MAR lacked documentation of Marcaine and the most recent EKG report dated 5/12/14 with note indicated that as date of the test.</p> <p>g. Pt #26 MAR indicated 10 ml Sensorcaine .5% local was administered at 12:26, standing orders pre-op, intra-op and post-op lacked indication of an order for Sensorcaine.</p>			

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S001152	<p>h. Pt #27 MAR indicated 10 ml Sensorcaine .5% local was administered at 09:09, standing orders pre-op, intra-op and post-op lacked indication of an order for Sensorcaine.</p> <p>i. Pt #30 MAR indicated triple antibiotic ointment (B) 0.9 gm topical was administered at 13:53, standing orders lacked an order for triple antibiotic ointment.</p> <p>2. Review of the document Subject: Medication Administration, last reviewed 8/14, indicated in the section titled Policy: Medications shall be ordered, administered, and recorded according to accepted standards of practice...</p> <p>3. In interview on 10/1/14 at 1:30pm, A2, Operations Manager, confirmed the above information and no further documentation was provided prior to exit.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(3)(B)</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>(3) Provision must be made for the</p>			

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NAME OF PROVIDER OR SUPPLIER  KLEINERT KUTZ SURGERY CENTER IN AFFILIATION W/ FLO	STREET ADDRESS, CITY, STATE, ZIP CODE 3605 NORTHGATE CT, STE 101 NEW ALBANY, IN 47150
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	<p>periodic inspection, preventive maintenance, and repair of the physical plan and equipment by qualified personnel as follows:</p> <p>(B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.</p> <p>Based on document review and interview, it could not be determined that the facility provided appropriate frequency of all mechanical equipment preventive maintenance in three (3) instances.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the document titled Emergency Generator Log indicated load tests and inspection dates as 1/28/13, 2/12/14, 3/28/14, 4/8/14, 5/4/14, 6/4/14, 7/1/14, 8/1/14 and 9/3/14.</li> <li>2. In interview on 9/29/14 at 4:00pm, A3, property manager, indicated generator tests are performed monthly and the manual is in the binder provided.</li> <li>3. Review of the binder provided lacked inclusion of the operating manual for the generator.</li> <li>4. In interview on 10/1/14 at 3:30pm, A4, director of facilities, indicated the</li> </ol>	S001152	<ol style="list-style-type: none"> <li>1 The operation manual for the generator is now in house It was obtained by the Director of Facilities The laptop for the EKG procedures was inspected and tested along with the leads on 10-27-14 by the biomedical engineering company and documented Cleaning of the laptop will be documented as well The manual for the code/nurse call system has been obtained and will be kept on location by the Director of Facilities</li> <li>2 The manuals will be kept in house on location by the Director of Facilities and documentation of cleaning of the laptop will be maintained</li> <li>3 Director of Facilities, Manager of Operations, and Administrator</li> <li>4 11-21-14</li> </ol>	11/21/2014

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	<p>manual was purchased today and is on it's way.</p> <p>5. Review of facility documents lacked evidence of preventative maintenance for the EKG (electrocardiograms) machines and the code call system.</p> <p>6. In interview on 10/1/14 at 3:00pm, administrator A2 indicated the nurse code/call system preventative maintenance was evident by documentation of code drills. Manufacturer manual was requested at that time. No further documentation was provided.</p> <p>7. In interview on 10/1/14 at 2:40pm, manager of operations A1 indicated the EKG machines were a program as part of the computer system and the facility used no standing for EKG. The program manual and computer manuals were requested at that time. No further documentation was provided.</p> <p>8. In interview on 10/1/14 at 3:15pm, staff RN A4 indicated the information technology (IT) staff performed updates as recommended by HP1 and that the EKG program information, according to IT, only contained installation information. A4 further indicated the computers used for the EKG program were on lease and were changed out every three (3) years, but that no PM was done in between times.</p> <p>9. In phone interview on 10/1/14 at</p>			

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S001166	<p>3:25pm, IT #1 indicated the program and software used for the EKG system did not require preventive maintenance and that computer updates were done as alerts came from M1. IT#1 indicated they use two (2) HP1 machines for the EKG program and that HP1 does not have recommended PM for the machines and that no manuals were kept in the facility for the HP1s. IT#1 disaffirmed having documentation or schedules for general inspection and cleaning of the equipment.</p> <p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(ii)</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>(4) The patient care equipment requirements are as follows:</p> <p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p> <p>(ii) There must be evidence of preventive maintenance on all patient care equipment.</p> <p>Based on document review and interview, the facility failed to provide</p>	S001166	1 The laptop and leads were inspected and tested and documented on 10-27-14 A	11/21/2014			

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	<p>evidence of preventative maintenance on all patient care equipment in one (2) instances.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>Review of facility documents lacked evidence of preventative maintenance for the EKG (electrocardiograms) machines and the code call system.</li> <li>In interview on 10/1/14 at 3:00pm, administrator A2 indicated the nurse code/call system preventative maintenance was evident by documentation of code drills. Manufacturer manual was requested at that time. No further documentation was provided.</li> <li>In interview on 10/1/14 at 2:40pm, manager of operations A1 indicated the EKG machines were a program as part of the computer system and the facility used no standing for EKG. The program manual and computer manuals were requested at that time. No further documentation was provided.</li> <li>In interview on 10/1/14 at 3:15pm, staff RN A4 indicated the information technology (IT) staff performed updates as recommended by HP1 and that the EKG program information, according to IT, only contained installation information. A4 further indicated the computers used for the EKG program</li> </ol>		<p>cleaning schedule is being developed for a quarterly cleaning and/or more frequently if needed</p> <p>An operation manual for the laptop is being explored with the IT Department The operation manual for the code/call system is in house on location and is maintained by the Director of Facilities</p> <p>The code/call system was last inspected and documented on 10-4-14</p> <ol style="list-style-type: none"> <li>The manuals, documentation of inspections, and cleaning documentation will be performed and maintained by the Director of Facilities</li> <li>Director of Facilities, Manager of Operations, and Administrator</li> <li>11-21-14</li> </ol>				

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	were on lease and were changed out every three (3) years, but that no PM was done in between times.  5. In phone interview on 10/1/14 at 3:25pm, IT #1 indicated the program and software used for the EKG system did not require preventive maintenance and that computer updates were done as alerts came from Microsoft. IT#1 indicated they use two (2) HP1 machines for the EKG program and that HP1 does not have recommended PM for the machines and that no manuals were kept in the facility for the HP's. IT#1 disaffirmed having documentation or schedules for general inspection and cleaning of the equipment.				