

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001065	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 11/28/2012
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NAME OF PROVIDER OR SUPPLIER SURGERY CENTER THE	STREET ADDRESS, CITY, STATE, ZIP CODE 7900 W JEFFERSON BOULEVARD, SUITE 102 FORT WAYNE, IN 46804
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S0000	<p>This visit was for a licensure survey.</p> <p>Facility Number: 009566</p> <p>Survey Date: 11/26-28/12</p> <p>Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 12/06/12</p> <p>1/23/2013 revised due to IDR</p>	S0000		
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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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S0110	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (a)(5)</p> <p>The governing body shall do the following:</p> <p>(5) Review, at least quarterly, reports of management operations, including, but not limited to, quality assessment and improvement program, patient services provided, results attained, recommendations made, actions taken, and follow-up.</p> <p>Based on document review and interview, the governing board failed to perform a quarterly review of quality assessment (QA) program reports for 3 of 4 quarters in 2012.</p> <p>Findings:</p> <p>1. Center documentation indicated that governing board meetings were held on 3-27-12 and 11-07-12. Board meeting agenda dated 11-07-12 failed to indicate that QA functions including transfers, infection control, medication errors, adverse patient responses and safety program functions were reviewed.</p> <p>2. During an interview on 11-28-12 at 1100 hours, staff A1 confirmed that the governing board held two meetings in 2012 and confirmed that meeting minutes for the 11-07-12 were not available for</p>	S0110	<p>There was a vacancy in the Director position for 2 months which is not a reason to miss the quarterly board meetings. During the transition the new Director was orienting and trying to put together a Bd mtg. The Board has been notified that they will have quarterly meetings in 2013. These meetings will take place Jan/Feb, April/May, July/Aug, Oct/Nov. The meeting agenda has been templated so that the necessary items will be discussed at the meeting. The meeting agenda will include the QA functions going forward that were not discussed at the last meeting: transfers, infection control, medication errors, adverse patients events and safety program. This will be the responsibility of the Director and Board Members.</p>	01/02/2013			

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	review. Staff A1 confirmed that they (A1) had attended the 11-07-12 meeting and confirmed that the board failed to review center activity regarding transfers, infection control, medication errors, adverse patient events and safety program administration.			

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S0153	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 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>Bases on document review and interview, the center failed to follow its policy/procedure and ensure that personnel were oriented to applicable policies and procedures for 2 contracted housekeeping personnel.</p> <p>Findings:</p> <p>1. The policy/procedure Housekeeping Services (approved 12-11) indicated the following: " A contract service company shall be provided with appropriate procedural guides for cleaning all areas of the center ...The director shall confirm with contract services that employees are instructed in proper procedures. "</p> <p>2. Review of 2 housekeeping personnel files (CS3 and CS4) failed to indicate that the staff were oriented to the housekeeping and infection control policy/procedures for cleaning at the</p>	S0153	<p>The Infection Control Officer will be responsible for the proper orientation of the contracted housekeeping staff. He will make sure he meets with the service to review orientation check off sheets and that they are correct and updated. He will make sure the contracted housekeeping staff have orientation sheets in their files. The Infection Control Officer will also begin to do a quarterly audit of the housekeeping service by doing random visits during cleaning hours. He will maintain the written audit in his infection control files.</p>	01/31/2013	

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	center. 3. During an interview on 11-27-12 at 1435 hours, staff A2 confirmed that the files lacked documentation of orientation to center cleaning practices.			

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S0164	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1 (c)(5) (H)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(H) A post offer physical examination and employee health monitoring in accordance with the center's infection control program.</p> <p>Based on policy and procedure review, employee health file review, and staff interview, the director failed to ensure that a post offer physical was performed for 1 of 4 staff hired in 2012 (staff member P1).</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12, review of the facility policies and procedures indicated that the policy in "Section III. A" on page 35, with a title of "Infection Control For Employee Health", and with a 1997 Edition date, indicated:</p> <p>a. on page 35 under "II. Procedure:", it reads: "A. Pre-Employment Physical Examination. 1. A pre-employment physical examination is performed by a physician..."</p> <p>2. at 10:35 AM on 11/18/12, review of personnel health files indicated:</p> <p>a. staff member P1, hired 6/25/12, had a</p>	S0164	The Director will be responsible to make sure all new hires have a pre-employment physical exam completed by a physician per current policy. All new hires will have proper paperwork in employee files. This will be completed for all new hires as of January 1, 2013.	01/02/2013

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	<p>form used for annual health updates, but lacked a physical form performed by a physician</p> <p>3. interview with staff member #50, the center Director, at 12:10 PM on 11/28/12 indicated:</p> <p>a. there was no physical performed by a physician for staff member P1 after their 6/25/12 employment date--an incorrect form was utilized at the time of hire</p>			

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S0176	<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 center failed to document contracted housekeeping personnel competency for cleaning and disinfecting surgical and patient care areas at the center for 2 personnel.</p> <p>Findings:</p> <p>1. Two housekeeping personnel files (CS3 and CS4) provided for review lacked documentation of cleaning and disinfecting competency in accordance with to the housekeeping and infection control policy/procedures for cleaning at the center.</p> <p>3. During an interview on 11-27-12 at 1435 hours, staff A2 confirmed that the files lacked documentation of personnel competency.</p>	S0176	<p>The Infection Control Officer will be responsible for the proper orientation of the contracted housekeeping staff. He will make sure he meets with the service to review orientation check off sheets and that they are correct and updated. He will make sure the contracted housekeeping staff have orientation sheets in their files. The Infection Control Officer will also begin to do a quarterly audit of the housekeeping service by doing random visits during cleaning hours. He will maintain the written audit in his infection control files.</p>	01/31/2013

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S0226	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(3)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.</p> <p>Based on document review, the center failed to maintain a list of all contracted services, including the scope and nature of services provided, for 6 of 39 services.</p> <p>Findings:</p> <p>1. The document Indirect Patient Care Contracted Services failed to indicate 6 providers (document disposal by V1, medical staff credentialing by V2 and four (4) fire systems and equipment providers V3, V4 V5 and V6) identified through a document review.</p> <p>2. On 11-28-12 at 1050 hours, staff A1 confirmed that the list of contracted services had not been maintained and lacked the indicated providers.</p>	S0226	<p>Director developed an updated list of all contracted services as well as quality indicators for each contract service. The new Quality Contract Services spreadsheet will be used in 2013 to track these services on a quarterly basis and also used to present at the Board meetings for QA review. The new Quality Contract Services spreadsheet will be taken to the QA committee and the Board for review at the next scheduled meeting - January/February 2013.</p>	12/21/2012

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S0230	<p>410 IAC 15-2.4-1 GOVERNING BODY; POWERS AND DUTIES 410 IAC 15-2.4-1(e)(5)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.</p> <p>Based upon document review and interview, the governing board failed to ensure a periodic review of the center was performed by a committee composed of a minimum of 3 physicians having no financial interest in the center.</p> <p>Findings:</p> <p>1. The Surgery Center Professional Staff Bylaws (approved 12-11) indicated the following: " The Utilization Review [UR] Committee shall be a standing committee meeting quarterly ...membership is made up of three professionals ...none of whom have a direct financial interest in the center. "</p> <p>2. The Surgery Center Utilization Review Program (approved 12-11) indicated the</p>	S0230	<p>The Director notified the Board that the current UR committee was not in compliance with the Med Staff Bylaws or State Regulations. The committee must have 3 physicians with no financial interest and currently one member is an owner. The Board responded via email to engage a possible replacement. The Board emailed the Director with the name of Dr. Saylor Daugherty, a retired ENT surgeon, who would be interested in sitting on the UR committee. Director contacted Dr. Daugherty to discuss responsibilities of position. Dr. Daugherty agreed to join the UR committee on 12/27/12. He will be meeting with the UR committee in January 2013 to do the 4th quarter 2012 chart reviews. The UR committee will report to the Director of any findings. The</p>	01/02/2013			

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	<p>following: " The UR committee shall meet quarterly. They shall provide a report and copy of their minutes to the Quality Assurance Committee ...Minutes of each committee meeting shall include the date of the meeting, the names of the committee members present and absent, confidential identification of each case reviewed, and a summary of cases reviewed. "</p> <p>3. On 11-26-12 at 1215 hours, staff A1 was requested to provide documentation of UR Committee minutes for the past 12 months and none was provided prior to exit.</p> <p>4. On 11-28-12 at 0950 hours, undated documentation observed in the 2012 Quality Assurance binder indicated that 31 medical records were reviewed by 2 physicians with no financial interest in the center (MD4 and MD11) and 1 physician with financial interest in the center (MD10). No UR committee minutes were observed with the documentation reviewed.</p> <p>5. During an interview on 11-28-12 at 1300 hours, staff A1 confirmed that the UR committee membership included a physician (MD10) with financial interest in the center. Staff A2 confirmed that the committee failed to maintain committee</p>		<p>Director will be responsible for reporting the UR committee report at the Board mtgs.The committee will meet quarterly in 2013 and reports provided to the Board on a quarterly basis.This is the responsibility of the Director to see that the new UR committee is not composed of any investors and meets quarterly.</p>		

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	<p>minutes in accordance with program requirements.</p> <p>6. During an interview on 11-28-12 at 1315 hours, staff A1 confirmed that the UR meetings were combined with the governing body meetings and that only two combined meetings on 3-27-12 and 11-07-12 were held in 2012. Staff A2 confirmed that the committee failed to meet quarterly in accordance with the medical staff bylaws.</p>			

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S0300	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)</p> <p>(a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: Based on document review and interview, the center failed to develop and maintain an organized and effective quality assessment and improvement program to ensure objective ongoing monitoring of all services and important aspects of care.</p> <p>Findings:</p> <p>1. The Quality Assurance [QA] Program (approved 11-12) indicated the following: " The QA committee receives and reviews all committee reports and minutes including ...transfers ...infection controland safety, fire and disaster activities ...The QA committee shall meet quarterly. They shall provide a report and copies of their minutes to both the Professional Staff and the Board of Directors. " The QA program description failed to indicate that contracted services and the required functions including discharges, medication errors, and response to patient</p>	S0300	The Director, Infection Control Officer and appointed staff will be reviewing the QAPI program to make sure it is comprehensive and complete. The center will maintain the QAPI program and make sure the QA committee (portion of Bd members) meets quarterly. The QA quarterly reports will be provided to the Board. The QA committee will assist in the review of the QAPI program making sure all aspects are covered: transfers, infection control, contract services, safety, fire and disasters, med errors, patient emergencies. The QAPI plan is currently under review and will be completed within the next 60 days.	01/31/2013			

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	<p>emergencies would be reviewed.</p> <p>2. Review of governing board meeting minutes dated 12-19-11 and 3-27-12 and agenda dated 11-07-12 failed to indicate an organized QA committee review of required functions including patient discharges and transfers. The board minutes failed to indicate QA committee activity for 2 of 4 quarters in 2012 and failed to indicate participation by the QA committee members for the 2 active meetings. The agenda dated 11-07-12 reported that no incident reports or sharps or work-related injuries for 2nd quarter 2012 and risk documentation indicated that 2 puncture injuries and a medication error occurred during the period.</p> <p>3. During an interview on 11-28-12 at 1100 hours, staff A1 confirmed that the center lacked an organized and effective QA program and confirmed that the committee members failed to meet for 2 of 4 quarters in 2012.</p>			

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S0310	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)(1)</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>(1) All services, including services furnished by a contractor. Based on document review and interview, the center failed to establish standards for evaluating its contracted services through its quality assurance (QA) program for 24 of 33 contracted services.</p> <p>Findings:</p> <p>1. The Quality Assurance Program (approved 11-12) failed to indicate a process for evaluating the contracted services through the center QA program.</p> <p>2. The center QA binder contained documentation titled Indirect Patient Care Vendors Statement of Quality for 24 contracted services (anesthesia machine service, biomedical engineering, coding/billing, copier/business machines, emergency response, generator service, housekeeping, 3 interpreter services, medical gas, medical record consulting, medical waste disposal, 2 medication suppliers, nutritional services, 3</p>	S0310	The Director will be responsible for seeing that the QA program includes a process to evaluate Contract Services. A Contract Services list was updated as well as quality measures and indicators for each service. This spreadsheet will be monitored on a quarterly/ongoing basis and reported to the Board on a quarterly basis. The quality measures and indicators will be used to monitor the effectiveness of the contracted service. This Quality Contract Services spreadsheet will be taken to the QA committee and the Board for review at the next scheduled meeting - January/February.	01/02/2013			

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	<p>pathology services, pharmacy consulting, radiology service, transcription service and 2 transfer facility agreements) that failed to indicate any standards for evaluating each service recommended for contract renewal.</p> <p>3. During an interview on 11-28-12 at 1030 hours, staff A1 confirmed that the QA program failed to establish measureable and objective standards for evaluating the indicated services and confirmed that the documentation failed to evaluate the effectiveness of each contracted service.</p>			

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S0320	<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 functions of transfers, medication errors, and response to patient emergencies were evaluated by the Quality Assurance (QA) committee.</p> <p>Findings:</p> <p>1. The Quality Assurance [QA] Program (approved 11-12) description failed to indicate the requirement to evaluate all functions including medication errors and response to patient emergencies through the QA program.</p> <p>2. Review of the governing board meeting agenda dated 11-07-12 failed to indicate that patient transfers or medication errors were reviewed by the</p>	S0320	<p>The Director, Infection Control Officer and appointed staff will be reviewing the QAPI program to make sure it is comprehensive and complete. The center will maintain the QAPI program and make sure the QA committee (portion of Bd members) meets quarterly. The QA quarterly reports will be provided to the Board. The QA committee will assist in the review of the QAPI program making sure all aspects are covered: transfers, infection control, contract services, safety, fire and disasters, med errors, patient emergencies. The QAPI plan is currently under review and will be completed within the next 60 days.</p>	01/31/2013			

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	<p>QA committee.</p> <p>3. Review of risk documentation indicated that a medication error occurred during the 2nd quarter 2012 period.</p> <p>4. Medical record review indicated that 6 patients (patient #'s 1, 3, 6, 12, 13 and 14) during the 2nd quarter 2012 period.</p> <p>4. During an interview on 11-28-12 at 1100 hours, staff A1 confirmed that the required functions had not been evaluated through the QA program.</p>			

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S0328	<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 patient care.</p> <p>Based on document review and interview, the center failed to document an appropriate action in response to opportunities for improvement identified through the Quality Assurance (QA) program.</p> <p>Findings:</p> <p>1. Review of governing board meeting minutes dated 12-19-11 and 3-27-12 failed to indicate that the QA committee identified an area for improvement in response to the services and functions subject to review at each meeting. The minutes lacked documentation of a committee recommendation or corrective action with ongoing monitoring of the action for its effectiveness.</p> <p>2. During an interview on 11-27-12 at</p>	S0328	The Director and appointed QA committee will review the current QAPI plan, made any recommendations and/or revisions needed to update the plan. The QAPI committee will meet quarterly in 2013. They will be responsible for maintaining the QA plan, reporting to the Board, making recommendation for improvement and seeing that action is implemented.	01/31/2013

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	1715 hours, staff A1 confirmed that the meeting minutes lacked documentation of areas for improvement identified by the QA committee and lacked documentation of committee recommendations and actions implemented in response to services and functions reviewed.			

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S0414	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(1)</p> <p>(f) The center shall establish a committee to monitor and guide the infection control program in the center as follows:</p> <p>(1) The infection control committee shall be a center or medical staff committee, that meets at least quarterly, with membership that includes, but is not limited to, the following:</p> <p>(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).</p> <p>(B) A representative from the medical staff.</p> <p>(C) A representative from the nursing staff.</p> <p>(D) Consultants from other appropriate services within the center as needed.</p> <p>Based on document review and staff interview, the facility failed to ensure that an infection control committee was established, failed to ensure that at least one member of the medical staff was involved in infection control practices, and failed to meet at least quarterly.</p> <p>Findings: 1. at 1:05 PM on 11/26/12, review of the facility policy manual indicated the</p>	S0414	The Director and Infection Control Officer will be responsible. There will be an Infection Control Committee set up to include the Infection Control Officer, a staff nurse, a surgical technician, and a physician. The committee will meet quarterly to review infection policies, practices, infections, cleaning practices, etc. The Infection Control Officer will be responsible for typing minutes of the meetings. The Infection Control Officer will attend the	01/31/2013

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	<p>document titled "Quality Assurance Program" (no policy number or date) stated on page 1 under "I. Policy and Authority:" in section B.: "The Quality Assurance Committee will carry out the following functions:...3. Shall provide surveillance of the center's infection potentials, review and analyze actual infections and recommend corrective programs to minimize infection hazards...8. Shall coordinate and integrate all committee activities. The Quality Assurance Committee receives and reviews all committee reports and minutes, including but not limited to: credentials; infection control; tissue review;...9. Shall develop standards for sanitation and medical asepsis..."</p> <p>2. Center documentation indicated that governing board/medical staff meetings were held on 3-27-12 and 11-07-12. The meeting agenda, dated 11/07/12, failed to indicate that infection control issues, concerns, and/or data were reported and reviewed.</p> <p>3. interview with staff member #50, the center Director, at 11:00 AM on 11/28/12 indicated:</p> <p>a. current facility policy has infection control integrated into the Quality Assurance Program</p> <p>b. there is no separate infection control</p>		<p>quarterly QA meetings and provide the minutes of the Infection Control Committee. The QA committee will then provide a report to the Board to review infection surveillance. The committee will be set up by January 31, 2013 and met as a committee at least once the first quarter of 2013.</p>		

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	<p>committee at the facility</p> <p>c. a physician does not participate as part of infection control or as director of infection control</p> <p>d. the infection control nurse/practitioner does not attend Quality Assurance committee meetings to report information related to surveillance or other infection issues</p> <p>e. the medical staff/governing board has not met quarterly in 2012 to review infection data, thus the infection control program has not met quarterly in 2012</p>			

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S0418	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(A)</p> <p>(2) The infection control committee responsibilities must include, but are not limited to the following:</p> <p>(A) Establishing techniques and systems for identifying, reviewing, and reporting infections in the center.</p> <p>Based on policy and procedure review and interview, the infection control committee and infection practitioner failed to implement the policy related to identifying patient post op infections.</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12, review of the policy manual indicated a policy titled "Infection Control Reporting" with Section XIII.A written at the bottom and page 4 also noted, that read:</p> <p>a. under section "II. Procedure", it indicated: "A. All physicians will be asked to report all suspected post operative infections to the Infection Control specialist or Director. Quarterly, each physician will be given a form which details the total number of procedures he/she performed for that particular quarter. The form asks them if any of their patients for this quarter had a post operative infection...If there were post operative infections, they are asked to list</p>			S0418	<p>This is the responsibility of the Infection Control Officer. There are quarterly forms sent to the physicians with their case numbers and the request to provide any SSI for that quarter. These forms are logged with Matt, the Infection Control Officer. The Infection Control Officer will start monitoring this on a monthly basis versus quarterly. The Infection Control Officer will take the results to the quarterly QA meeting and then they will be reported to the Board.</p>		01/31/2013

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	<p>the name of the patient, sign the form and return to the Infection Control specialist or Director..."</p> <p>b. under section "II. Procedure", it reads: "...4. The quarterly physician forms and the SSI (surgical site infections) forms will be filed in the Quality Assurance Manual..."</p> <p>2. interview with staff member #51, the infection control practitioner/specialist, at 12:15 PM on 11/28/12, indicated:</p> <p>a. the policy is not being implemented as written as no forms are being sent to the physicians either quarterly, or any other time frame, related to patients seen and asking them to report back with any post op infections that may have occurred post operatively</p>				

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S0428	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(i)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(i) Sanitation.</p> <p>Based on observation, document review and interview, the infection control practitioner failed to ensure the cleanliness and sanitation of equipment in three areas of the facility.</p> <p>Findings:</p> <p>1. at 1:00 PM on 11/27/12, while on tour of the surgery area of the facility, it was observed that the Steris/Amsco blanket warmer outside OR suite #1, was very dusty and with debris under the lower shelf of the upper fluid warming cabinet.</p> <p>2. at 1:30 PM on 11/27/12, interview with staff member #51, the center Director, indicated:</p> <p>a. it was confirmed that there were infection/sanitation issues with the top warming cabinet of the blanket warmer</p> <p>b. recently the lower cabinet unit required cleaning due to a build up of dust</p>	S0428	<p>Matt, Infection Control Officer, will develop a cleaning log book for the blanket warmer in OR. The warmer will be cleaned on a weekly basis as of January 2013. Matt and the Director informed the PACU staff that clean the PACU refrigerator that they need to remember to clean the door shelves and compartments when cleaning the refrigerator starting in January 2013. Log sheets are in place on the refrigerator and the Infection Control Officer will do spot checks at varied intervals to determine the cleanliness of the refrigerator for facility cleanliness. The Infection Control Committee will develop a terminal cleaning schedule for the OR staff that do the terminal cleaning. The Infection Control Committee will also review and approve the disinfectants used for cleaning and disinfecting the OR suite. The policy for Terminal Cleaning</p>	01/31/2013			

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	<p>c. both the upper and the lower cabinet units need to be on a routine cleaning schedule</p> <p>3. at 1:40 PM on 11/28/12, review of the "2012 Quarterly Defrost Schedule For Refrigerator in PACU (post anesthesia care unit)" indicated:</p> <p>a. the most recent refrigerator cleaning was on "Nov. 19, 2012"</p> <p>4. at 1:47 PM on 11/27/12, while on tour of the recovery room pantry area in the company of staff member #51, the infection control practitioner, it was observed that the full size drink refrigerator was dusty/dirty in the door compartments/shelves</p> <p>5. interview with staff member #51 at 1:47 PM on 11/27/12 indicated:</p> <p>a. nursing staff clean the refrigerator monthly but probably don't notice the shelves on the door</p> <p>6. The policy/procedure Terminal Cleaning of the Operating Room Suite (approved 12-11) failed to indicate the following:</p> <p>A. IC committee review and approval</p> <p>B. the IC committee-approved disinfectants to be used for cleaning and disinfecting the OR suite</p> <p>C. housekeeping personnel or center staff</p>		<p>will be revised to include the above as well as required personal protective equipment, schedule of terminal cleaning, list in order of cleaing areas which will start from high to low surfaces. A terminal cleaning log to include what was cleaned will be incorporated by February 15, 2013. The ENT Surgery Center Cleaning Specifications will be revised to note that the OR staff will do the OR suite terminal cleaning 5 days per week and not the contracted housekeeping service by January 31, 2013.</p>		

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	<p>responsibility for terminal OR cleaning</p> <p>D. personal protective equipment required when cleaning the OR suite</p> <p>E. a provision ensuring that all high-touch surfaces were cleaned and/or disinfected</p> <p>F. a specific process for surgery suite cleaning to prevent contamination of previously disinfected surfaces</p> <p>7. During an interview on 11-27-12 at 1300 hours, staff A1 confirmed that the policy/procedure lacked the indicated provisions.</p> <p>8. Documentation titled ENT Surgery Center 3-30-10 Cleaning Specifications provided by the contracted housekeeping service indicated that the personnel were cleaning the OR rooms 5 days a week according to a list of specific cleaning tasks. The organization of cleaning tasks failed to minimize the potential for contamination of previously disinfected surfaces in the OR by housekeeping staff.</p> <p>9. During an interview on 11-27-12 at 1400 hours, staff A2 confirmed that contracted housekeeping personnel were currently not performing terminal cleaning in the OR suites and confirmed that the housekeeping cleaning specifications failed to indicate current OR cleaning responsibilities.</p>			

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S0434	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(iv)</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>(iv) Aseptic technique, invasive procedures, and equipment usage.</p> <p>Based on policy and procedure review, observation, and staff interview, the infection control committee and practitioner failed to implement the facility policy related to surgical masks for 2 staff members, and failed to ensure that earrings were covered by the bouffant surgical cap for one scrub tech.</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12, review of the policy and procedure manual indicated a policy titled "Operating Room Attire" with Section X.A at the bottom of the page and 1997 Edition noted, that reads: a. under section "II. Procedure:", it reads: "...F. To prevent cross infection, masks should:...5. Not be allowed to hang around neck."</p> <p>2. on 11/27/12 at 1:05 PM, while on tour</p>			S0434	<p>The Director and Infection Control Officer are responsible for this correction. The staff was informed by the Director that according to AORN standards earrings must be confined within the bouffant cap. The policy on Operating Room Attire will be revised to include this AORN standard. The staff will be required to sign off on the revised policy. The staff and physicians were informed that per facility policy, masks are not to be worn dangling around the neck. They must be removed when leaving the OR suite. The Infection Control Officer will be responsible for enforcing this policy and AORN standard. He will continue to monitor that earrings are confined within the bouffant caps and that masks are not worn around the neck.</p>		01/31/2013

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	<p>of the surgery area of the facility, it was noted that the scrub tech in OR suite #2 was assisting in surgery with hoop earrings not confined within the bouffant surgical cap</p> <p>3. at 1:10 PM on 11/27/12, staff member #51, the infection control practitioner, confirmed that the scrub tech had earrings not confined within the bouffant cap as per AORN (association of perioperative nurses) standards and recommendations</p> <p>4. at 1:25 PM on 11/27/12, while on tour of the surgery area of the facility, it was observed that the physician and one nursing staff member were outside the OR suites in the hallway with surgical masks dangling about the neck</p> <p>5. staff member #50, the center Director, confirmed that the surgeon/physician and one nursing staff member were in the surgical hallway with surgical masks dangling about the neck</p> <p>6. at 1:50 PM on 11/27/12, the surgeon was observed to be in the PACU (post anesthesia care unit) with the surgical mask dangling about the neck</p> <p>7. at 12:15 PM on 11/28/12, interview with staff member #51, the infection control practitioner, indicated:</p>				

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	<p>a. AORN standards include language that earrings are to be confined within the bouffant head covering when scrubbed in for surgery</p> <p>b. currently, the facility policy for operating room attire does not include instructions to ensure that staff cover earrings within the bouffant head cover</p> <p>c. staff were not abiding by the facility policy for surgical masks by moving about the surgery area and recovery area with masks dangling about the neck</p>			

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S0442	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 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 and procedure review, personnel health file review, and staff interview, the infection control practitioner failed to implement the facility policy related to annual TB (tuberculosis) testing for 1 staff member (P2), and Varicella testing for one staff member (P1).</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12, review of the facility policies and procedures indicated that the policy in "Section III. A" on page 35, with a title of "Infection Control For Employee Health", and with a 1997 Edition date, indicated:</p> <p>a. on page 38 under "2. Tuberculosis", it reads: "...b. PPD (purified protein</p>			S0442	<p>The Director will be responsible for this correction. The facility policy on Infection Control for Employee Health is under review. The suggested revisions will be to add any employee that has a titer below the reference range or considered negative will have a booster completed. Evidence of the booster given will be placed in their employee file. The policy will also reference equivical results. Equival results will have a retest and if the results is still equivical, the employee will be instructed to have a booster and evidence of the booster will be placed in their file. All new hires will be given TB test per policy. Currently the policy states a 2 step TB will be completed. The Director and RN</p>		01/14/2013

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	<p>derivative) Testing. i. PPD testing is mandatory for all employees. ii. Two step PPD tests will be give to all new employees. Annual PPD testing will be administered to all employees."</p> <p>b. on page 38 under "3. Measles, mumps, rubella (MMR) and varicella a. Employees should submit evidence of previous inoculations 1. If no evidence of inoculations exist MMR and varicella boosters are advised. Titters may then be drawn for evidence of antibodies."</p> <p>2. at 10:35 AM on 11/18/12, review of personnel health files indicated:</p> <p>a. staff member P1, hired 6/25/12, had a negative Varicella titer (form dated 8/20/12 with a "reference range" of 0.00 to 0.90, a result of <0.91 and "negative" on the document)</p> <p>b. staff member P2, hired 8/22/12, had a most recent TB test form dated 10/16/10 in the file</p> <p>3. interview with staff member #50, the center Director, at 12:10 PM on 11/28/12 indicated:</p> <p>a. it was unknown that the Varicella for P1 was negative</p> <p>b. the current policy does not have a specific plan for how to handle equivocal or negative titer results</p> <p>c. staff member P2 should have had a two step PPD done at the time of hire</p>		responsible for TB testing will be responsible for completing this for all new hires.				

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S0640	<p>410 IAC 15-2.5-3 MEDICAL RECORDS, STORAGE, AND ADMIN. 410 IAC 15-2.5-3(e)(1)</p> <p>(e) All entries in the medical record must be as follows:</p> <p>(1) Legible and complete. Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to ensure that medical records were complete and legible for 11 of 14 patient records (pts. #1, 4, 5, 6, 8, 9, 10, 11, 12, 13, and 14).</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12, review of the policy manual indicated a policy titled: "Medical Records" with Section VIII.A at the bottom of the page and 1997 Edition also written at the bottom of the page, read:</p> <p>a. page 2 under "Medical Records I. Policy:" reads: "A. The Center shall maintain medical records on all patients that are documented accurately and in a timely manner..."</p> <p>b. page 4 under "Required Documentation", reads: "...B. Portions of the Medical Record. 1. Identification Data. a. Pertinent information in order to identify the patient... 12. Transfer Form (if necessary). a. should the patient be transferred to another acute care health facility, a Transfer Form will be</p>	S0640	The Director will be responsible for this correction. The Director typed up the deficiencies on this report regarding Medical Record Deficiencies. All indications were presented to the staff. The staff reviewed these deficiencies and signed off on the written information so that they are aware of the documentation deficiencies. Reviewed with staff the policy on correcting errors. The chart auditors (staff) were also informed to be more cognizant on their chart audits and watch for missing patient labels, missing signatures, missing information. The Director also typed up the deficiencies related to the Anesthesia Record and presented the notes to the Anesthesia providers. Reminded them to watch for complete documentation and the process for correcting errors.	01/14/2013			

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	<p>completed and included in the patient record..."</p> <p>c. page 7 under "General Rules", reads: "...II. Procedure:...C...All entries on the chart shall be legible, factual and in chronological order..."</p> <p>d. page 8 under "Corrections", reads: "I. Policy: A. When inaccurate entries are made in the medical record, they will be changed properly. II. Procedure: A. Entries shall be changed in the following manner: 1. Draw a single line through the entry. 2. Write "error" above or below the entry. 3. Record date and/or time of the error. 4. Sign or initial by the person changing the entry..."</p> <p>e. page 23 under "Analyzing Discharged Records for Deficiencies" read: "I. Policy: A. to assure that all required information in a patient's record is accurate, complete, dated and signed by the appropriate individuals..."</p> <p>2. at 1:05 PM on 11/26/12, review of the policy manual indicated a policy titled: "Anesthesia Safety Rules" with Section V.A and 1997 Edition written at the bottom of the page, read:</p> <p>a. on page 6 under section "B. Anesthesia Machines": "1. All equipment used for the administration of anesthesia and respiratory assistance should be checked for defects, malfunctions, leaks, improper hose</p>			

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	<p>connections, and anesthetic agents by the anesthesiologist prior to using the equipment..."</p> <p>3. Review of patient medical records indicated:</p> <p>a. pt. #1:</p> <p>I. had no patient identification information on the "Additional Post Op Nursing Notes" page</p> <p>II. lacked documentation of a dismissal time on either the "Additional Post Op Nursing Notes" page or the "Post Anesthesia Care Record" form</p> <p>III. had correction to an error on the "Additional Post Op Nursing Notes" page that was not corrected per facility policy</p> <p>b. pt. #4 had no patient identification on the "Transfer Checklist" form or on the "Additional Post Op Nursing Notes" page</p> <p>c. pt. #5:</p> <p>I. had an error crossed out and not corrected per facility policy on the physician order form</p> <p>II. had meds crossed out and lacked correction of the error per facility policy on the "Operative Record" form (back side in the medications area at the bottom of the page)</p> <p>III. lacked documentation of any type of allergy on the "Anesthesia Record" form</p> <p>d. pt. #6 had write overs on the "Post Anesthesia Care Record" form</p> <p>e. pt. #8 had:</p>			

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	<p>I. no patient identification on the "Transfer Form"</p> <p>II. no medical history, diagnosis, or anesthesia history documentation on the "Anesthesia Record" form</p> <p>III. write overs on times (end of anesthesia time and time of the post anesthesia check) on the "Anesthesia Record" form</p> <p>IV. no pre op safety check documented on the "Anesthesia Record" form</p> <p>V. write overs on the "Post Anesthesia Care Record" form</p> <p>f. pt. # 9 had no identification on the "Transfer Form"</p> <p>g. pt. #10 lacked documentation by the anesthesiologist of whether or not the patient "met criteria for medical discharge from anesthesia services" at the bottom of the "Anesthesia Record" form</p> <p>h. pt. # 11 had an incomplete "Transfer Checklist" form</p> <p>i. pt. #12 had:</p> <p>I. no patient identification on the "Transfer Checklist" form</p> <p>II. had meds crossed out and lacked correction of the error per facility policy on the "Operative Record" form (back side in the medications area at the bottom of the page)</p> <p>III. lacked a "Transfer Form" (had only a Transfer Checklist)</p> <p>j. pt. #13 lacked documentation related to anesthesia history on the "Anesthesia</p>			

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	<p>Record" form</p> <p>k. pt. #14 had:</p> <p>I. lacked patient identification on the "Additional Post Op Nursing Notes" page</p> <p>II. write over on the post anesthesia assessment time and had documentation of the post anesthesia time occurring prior to the end of anesthesia time (not in chronological order)</p> <p>4. interview with staff member #50, the center Director, at 12:10 PM on 11/28/12 indicated:</p> <p>a. after review of the medical records listed in 2. above, it was determined that patient identification is lacking from some patient record forms; errors are not corrected per policy; and anesthesia lacks documentation on their form as listed</p>				

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S0736	<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 and interview, the medical staff failed to follow its Bylaws and ensure that the medical staff met quarterly.</p> <p>Findings:</p> <p>1. On 11-26-12 at 1215 hours, staff A1 was requested to provide documentation of medical staff meetings and none was provided prior to exit.</p> <p>2. The Surgery Center Professional Staff Bylaws (approved 12-11) indicated the following: " Professional Staff Meetings ...Staff meetings shall be at least quarterly. "</p> <p>3. During an interview on 11-28-12 at 1315 hours, staff A1 confirmed that the medical staff meetings were combined</p>			S0736	<p>The Director, Board and Medical Staff will be responsible for this correction. The medical staff will have quarterly meetings which will be combined with the Board Meetings. The Board meetings and staff meetings for 2012 were not held quarterly due to vacancies in the Director position for 2 months. The 4th quarter meeting was planned to be held in late December however due to extreme surgery schedules and physicians out of the office it will be moved to January 2013. There will be quarterly Board/Medical Staff Meetings in 2013 - January/February, April/May, July/August, and October/November.</p>		01/07/2013

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	with the governing body meetings and that only two combined meetings on 3-27-12 and 11-07-12 were held in 2012.				

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S0742	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(C)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(C) A provision for maintaining records of all meetings of the medical staff and its committees. Based upon document review and interview, the medical staff failed to document quarterly medical staff meetings.</p> <p>Findings:</p> <p>1. On 11-26-12 at 1215 hours, staff A1 was requested to provide documentation of medical staff meetings and none was provided prior to exit.</p> <p>2. During an interview on 11-28-12 at 1315 hours, staff A1 confirmed that the medical staff meetings were combined with the governing body meetings and confirmed that no documentation of separate medical staff meetings was available.</p>	S0742	<p>The Director, Board and Medical Staff will be responsible for this correction. The medical staff will have quarterly meetings which will be combined with the Board Meetings. The Medical Staff meeting will have separate meeting minutes from the Board meeting minutes. The Board meetings and staff meetings for 2012 were not held quarterly due to vacancies in the Director position for 2 months. The 4th quarter meeting was planned to be held in late December however due to extreme surgery schedules and physicians out of the office it will be moved to January 2013. There will be quarterly Board/Medical Staff Meetings in 2013 - January/Feb, April/May, July/August, and October/November.</p>	01/07/2013			

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S0780	<p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(N)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.</p> <p>Based on review of the medical staff rules and regulations, policy and procedures, patient medical records, and staff interview, the facility failed to ensure that verbal orders were written and authenticated per facility policy for 4 of 14 patient records (pts. # 5, 10, 12 and 14).</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12, review of the facility policy manual revealed "Professional Staff Rules and Regulations" with Section II.B and 1997 Edition written at the bottom of the page, that read:</p> <p>a. under "I. General Considerations" on page 2, read: "...G. All orders for treatment shall be in writing...All verbal</p>	S0780	<p>The Director will be responsible. The Medication Administration Policy has been revised to remove Verbal Orders on this policy. There is a separate policy for Verbal Orders. This will keep policies more concise and easy to maintain without duplication. The policy on Required Documentation was also revised to exclude notations for Verbal Orders as this also created duplication and confusion. All policy and procedure regarding Verbal Orders will be listed on the Verbal Order Policy. Verbal Order Policy has been revised to accommodate the correct regulations for authentication and time of signatures. The staff was informed of the revised Verbal Order Policy. They will now date and sign their verbal orders per</p>	01/14/2013			

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	<p>and telephone orders shall be written, dated and signed...H. General policies of the center as adopted by the board of Directors, shall be part of these Rules and Regulations..."</p> <p>2. at 1:05 PM on 11/26/12, review of the facility policy manual revealed "Medication Administration" with Section XII.A and 1997 Edition written at the bottom of the page, that read: a. under "II. Procedure", it reads: "...b. Verbal orders, including telephone orders. i. R.N.'s (registered nurses) and L.P.N.'s (licensed practical nurses) may receive verbal orders. The order must be promptly recorded in the patient's medical record, noting the name of the person giving the verbal order, time, date and the full signature of the individual receiving the order. ii. The physician must co-sign the verbal or telephone order within twenty-one (21) business days..."</p> <p>3. at 1:05 PM on 11/26/12, review of the facility policy manual revealed "Required Documentation" with Section VII.A and 1997 Edition written at the bottom of the page, that read: a. on page 5 under "7. Orders.", it reads: "a...All verbal orders shall be signed/authenticated by the attending physician at the time of the order or within thirty (30) business days."</p>		<p>the policy with VO/RV for repeat and verified. The physicians have been informed via email communication and verbally that they need to sign, date and time their signatures for verbal orders. Verbal orders will be reviewed to be in compliance with facility policy for signing, dating and timing during continual chart audits.</p>		

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	<p>4. at at 1:05 PM on 11/26/12, review of the facility policy manual revealed "Verbal Orders" with Section VIII.A and 1997 Edition written at the bottom of the page, that read:</p> <p>a. under "II. Procedure:", it reads: "...D. The receiver will always repeat the order back to the giver to verify that it is understood and correct. E. The receiver will record the order in the medical record, sign or initial the entry, and identify it as V.O. (Verbal Order), or T.O. (Telephone Order)...1. all verbal orders will be signed/authenticated by the physician within thirty (30) business days."</p> <p>5. review of patient medical records indicated:</p> <p>a. pt. # 5 had a verbal order written on 7/23/12 for a "Stat EKG" that lacked a time of the order, lacked a repeat and verified notation, and lacked physician authentication of the order</p> <p>b. pt. # 10:</p> <p>I. had a verbal order for Albuterol written on 10/29/12 that lacked a time of the order and lacked a repeat and verified notation</p> <p>II. lacked a date with the physician's authentication that would indicate the physician signed the order within the time frame of the facility policy</p>			

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	<p>c. pt. # 12:</p> <p>I. had two verbal orders written on 6/14/12 that lacked the time of the orders and lacked notation of repeat and verified with the first order</p> <p>II. lacked a date with the physician's authentication that would indicate the physician signed the order within the time frame of the facility policy</p> <p>d. pt. #14:</p> <p>I. had a verbal order for Robinul written on 5/2/12 that lacked a time of the order and lacked a repeat and verified notation</p> <p>II. lacked a date with the physician's authentication that would indicate the physician signed the order within the time frame of the facility policy</p> <p>6. interview with staff member #50, the center Director, at 9:30 AM and 12:15 PM on 11/28/12 indicated:</p> <p>a. after review of the patient medical records listed in 5. above, it was determined that nursing staff are not timing verbal orders and are not following policy related to documenting repeat and verification of the verbal orders</p> <p>b. if physicians don't date their authentication of the verbal orders, it cannot be determined that they are signed within the appropriate time frame</p> <p>c. two policies contradict themselves as to when verbal orders must be</p>						

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	authenticated--one reads 21 days and another reads 30 days (as long as the nursing staff write "repeat and verify")			

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S1010	<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, including, but not limited to, the following:</p> <p>(A) Drug handling, storing, labeling, and dispensing.</p> <p>Based on policy and procedure review, document review, observation, and staff interview, the facility failed to ensure that expired medications were removed from the drug storage areas (emergency drug cabinet and Malignant Hyperthermia kit) as per facility policy.</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12, review of the facility policy manual indicated a policy titled "Inspection of Drug Storage Area", with Section XII.A at the bottom of the page and 1997 Edition written at the bottom middle of the page, that reads:</p> <p>a. under "I. Policy", it reads: "A. The Director or designee conducts, at least monthly, inspections of all areas where medications are administered or stored, to assure quality control of medications."</p> <p>b. under "II. Procedure", it reads: "A. A file of the monthly inspection of each</p>	S1010	<p>The Director will be responsible. Policies for Drug Handling and Storage have been revised and will be taken to the next QA mtg and Board mtg (in January/February 2013) for review/approval. The policies on Drug labeling and dispensing have also been reviewed and revised. These will also go to QA and Board in January/February 2013 for review/approval. The nurse responsible for the MH and Crash Cart medications has been met with and will maintain more appropriate records of the expired medications and the backorder situation. The sodium bicarb has been a difficult order item for months and we re-ordered after the survey again from 2 different distributors and it is still on backorder. The hospital will only give us sodium bicarb that they have mixed themselves and the shelf life is only 30 days. They will not promise to provide us with</p>	01/21/2013	

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	<p>drug storage area is maintained to verify that...3. Outdated and otherwise unusable drugs have been identified and their distribution and administration prevented..."</p> <p>2. at 1:40 PM on 11/28/12, review of the monthly drug check document form and the "Dantium Cart" form both indicate that Sodium Bicarbonate (4 total) were to expire "9/12"</p> <p>3. at 1:40 PM on 11/28/12, review of the October and November "Crash cart Defibrillator Check Sheet" indicated that in October the "drug's checked" was on 10/1/12 and in November, "drugs checked" was on 11/5/12</p> <p>4. on 11/27/12 at 1:06 PM, it was observed in the emergency drug cart (located outside OR suite #2) that:</p> <p>a. one 500 ml bag of IV (intravenous) Lactated Ringger's solution had expired 1/12</p> <p>b. one 8.4% Sodium Bicarb 50 meq expired August 1, 2012</p> <p>5. at 1:10 PM on 11/27/12, staff member #51, the infection control practitioner, confirmed that the Lactated Ringgers and Sodium Bicarb were both expired</p> <p>6. at 1:30 PM on 11/27/12, in the</p>		<p>this ongoing but will be dealt with when asking for more. The crash cart and MH cart will be reviewed and revised by mid January 2013. New carts have been ordered, as well as organizing bins. The medications will be reviewed by staff and anesthesia before completing updated cart. A new check off sheet will be developed so that every item will be listed by drawer and have a column for any expiration dates on supplies as well as medications. This will better assist the staff with expiration dates during the cart check offs.</p>		

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	<p>Malignant Hyperthermia kit, it was observed that 2 Sodium Bicarb 8.4% 50 meq had expired August 1, 2012</p> <p>7. staff member #50, the center Director, confirmed at 1:35 PM on 11/27/12 that the Sodium Bicarb 8.4% 50 meq (#2) had expired August 1, 2012</p> <p>8. at 1:35 PM on 11/27/12, interview with staff member #53, the RN (registered nurse) who performs the monthly drug checks, indicated:</p> <p>a. several drugs have been back ordered for months and unavailable</p> <p>b. three different suppliers are used to provide medications and supplies needed</p> <p>9. at 3:45 PM on 11/27/12, review of the CuraScripts invoices provided indicated 4 Sodium Bicarb were listed as ordered on 7/30/12 and were back ordered with no date of possible availability noted</p> <p>10. interview with staff member #51, the infection control practitioner, at 4:00 PM on 11/27/12 indicated:</p> <p>a. the CuraScript company will automatically ship the back ordered product if it becomes available within 60 days after ordering</p> <p>b. after 60 days, the facility must reorder the product, it will not be automatically shipped</p>			

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	<p>c. it is unknown if the Sodium Bicarb were re ordered 9/30/12 (60 days after first ordering on 7/30/12)</p> <p>d. the facility has no documentation of how meds and products are tracked to be sure that they are reordered if 60 days elapses</p> <p>11. even though 2 other providers were said to have been contacted for back ordered products/meds and also not available, no further documentation was provided prior to exit that would corroborate this</p>			

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S1044	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(5)</p> <p>Pharmaceutical services must have the following:</p> <p>(5) A list of available emergency drugs.</p> <p>Based on document review, observation, and staff interview, the facility failed to ensure that the emergency drugs on the list were available in the event of an emergency.</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12 and 3:40 PM on 11/28/12, review of emergency drug list (with accompanying expiration date for monthly checks), indicated 1 Lasix and 1 Mannitol should be present in the emergency drug cart/cabinet</p> <p>2. at 1:06 PM on 11/27/12, it was observed in the emergency drug cabinet outside of OR suite #2 that the slots/compartments for Lasix (furosemide) and Mannitol were empty</p> <p>3. staff member #50, the center Director, confirmed at 1:35 PM on 11/27/12 that the slots/compartments for Lasix (furosemide) and Mannitol were empty</p> <p>4. at 1:35 PM on 11/27/12, interview with staff member #53, the RN (registered</p>	S1044	<p>The Director and nursing staff will be responsible. The nurse responsible for the MH and Crash Cart medications has been met with and will maintain more appropriate records of the expired medications and the backorder situation. The lasix and mannitol have been a difficult order item for months and we re-ordered after the survey again from 2 different distributors and it is still on backorder. The hospital will not supply us with these either as their supply is also low. They will not promise to provide us with this ongoing but will be dealt with when asking for more. The RN was advised to keep a log of conversations and orders for these backorder drugs. The crash cart and MH cart will be reviewed and revised by mid January 2013. New carts have been ordered, as well as organizing bins. The medications will be reviewed by staff and anesthesia before completing updated cart. A new check off sheet will be developed so that every item will be listed by drawer and have a column for any expiration dates on supplies as well as medications. This will</p>	01/21/2013	

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	<p>nurse) who performs the monthly drug checks, indicated:</p> <ul style="list-style-type: none"> a. several drugs have been back ordered for months and unavailable b. three different suppliers are used to provide medications and supplies needed <p>5. at 3:45 PM on 11/27/12, review of the CuraScripts invoices provided indicated:</p> <ul style="list-style-type: none"> a. 2 Mannitol were ordered on 2/27/12 and 10/1/12 and listed as back ordered with no date of possible availability noted b. 1 Lasix was ordered on 3/26/12 and listed as back ordered with no date of possible availability noted <p>6. interview with staff member #51, the infection control practitioner, at 4:00 PM on 11/27/12 indicated:</p> <ul style="list-style-type: none"> a. the CuraScript company will automatically ship the back ordered product if it becomes available within 60 days after ordering b. after 60 days, the facility must reorder the product, it will not be automatically shipped c. it is unknown if the Sodium Bicarb were re ordered 9/30/12 (60 days after first ordering on 7/30/12) d. the facility has no documentation of how meds and products are tracked to be sure that they are reordered if 60 days elapses 		better assist the staff with expiration dates during the cart check offs. The RN will also be able to make comments such ordered 'date'/BO, etc.	

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	7. even though 2 other providers were said to have been contacted for back ordered products/meds and also not available, no further documentation was provided prior to exit that would corroborate this			

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S1142	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(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>(1) No condition in the center or on the grounds may be maintained which may be conducive to the harboring or breeding of insects, rodents, or other vermin.</p> <p>Based on document review and interview, the center failed to establish and maintain a provision for periodic pest control monitoring and treatment at the center.</p> <p>Findings:</p> <p>1. On 11-26-12 at 1215 hours, staff A1 was requested to provide documentation of periodic pest control monitoring at the center and none was provided prior to exit.</p> <p>2. During an interview on 11-28-12 at 1245 hours, staff A1 indicated that a contracted service pest control provider for the medical office building was monitoring and treating the exterior and public areas at the building and indicated that no periodic monitoring or treatment</p>	S1142	<p>The Director will be responsible. On 12/4/12 the Director called Orkin Pest Control and spoke with Sam regarding the current pest control contract. Director asked that they provide a quarterly monitoring system of the facility and provide a quarterly report or feedback. Sam agreed to do a quarterly surveillance and will provide a log book on site for the surveillance report beginning in January 2013.</p>	01/07/2013			

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	for the surgery center was currently being performed.				

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S1146	<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 employees.</p> <p>Based on policy and procedure review, observation, and staff interview, the facility failed to ensure that no hazard was created in relation to patient care in regard to the glucometer control solutions that were not maintained as per manufacturer's instructions, expired pregnancy testing control solution, and expired products in the emergency/crash cart.</p> <p>Findings:</p> <p>1. at 1:05 PM on 11/26/12, review of the policy dated 12/09 and titled "Bayer Contour Meter Instructions and Infection Control Guidelines", indicated there is nothing written in the policy related to the expiration of control solutions used in testing the meter</p> <p>2. at 1:40 PM on 11/27/12, review of the package insert for the Bayer Contour</p>	S1146	The Director will be responsible. The Bayer Contour Meter Policy has been revised to include information on the expiration of the control solutions. The expiration on the control solutions is 6 months from opening. The staff have reviewed the revised policy and have been informed of the 6 month expiration date on the control solutions. The staff has been instructed to date the vials with the 6 month expiration date when opening a new vial. The crash cart and MH cart will be reviewed and revised by mid January 2013. New carts have been ordered, as well as organizing bins. The medications will be reviewed by staff and anesthesia before completing updated cart. A new check off sheet will be developed so that every item will be listed by drawer and have a column for any expiration dates on supplies as	01/14/2013			

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	<p>control solutions indicated:</p> <p>a. "...It is important not to use the control if the expiry [sic] date printed on the bottle label and carton has passed or it has been six months since you first opened the bottle. It will help to write the six month discard date on the label in the area provided when you first open the control..."</p> <p>3. at 1:45 PM on 11/27/12, review of the pre op area control solution log with dates of testing and dating of bottle changes indicated:</p> <p>a. a "new bottle" was noted on 8/31/11 and then on 3/30/12 (six months from 8/31/11 would have been the end of February 2012 and six months from 3/30/12 would have been 9/30/12)</p> <p>4. at 1:35 PM on 11/27/12, while on tour of the pre operative area in the company of staff member #52, the pre op RN (registered nurse), it was observed that:</p> <p>a. the Bayer control solution was not dated with a discard date</p> <p>b. the "HCG" pregnancy test control solution expired 11/4/12</p> <p>5. at 1:50 PM on 11/27/12, while on tour of the recovery room area in the company of staff member #51, the infection control practitioner, it was observed that the Bayer control solution was not dated with</p>		<p>well as medications. This will better assist the staff with expiration dates during the cart check offs. The RN will also be able to make comments such ordered 'date'/BO, etc. Staff have been reminded to monitor expiration dates on medications and supplies on a monthly basis.</p>				

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	<p>a discard date</p> <p>6. interview with staff member #51, the infection control practitioner, at 12:15 PM on 11/28/12 indicated:</p> <p>a. it was unknown by this staff member that the control solutions had an expiration date other than that printed on the vial by the manufacturer, and that this 6 month date was to be noted on the vial when first opened</p> <p>b. the current facility policy related to the Bayer Contour meter does not address expiration of the control solution and marking the 6 month expiration date on the vial when opened</p> <p>7. at 1:40 PM on 11/28/12, review of the October and November "Crash cart Defibrillator Check Sheet" indicated that in October the cart was checked on 10/1/12 and in November, on 11/5/12</p> <p>8. on 11/27/12 at 1:06 PM and 3:50 PM, while in the company of staff member #51, the infection control nurse, it was observed in the emergency drug cart (located outside OR suite #2) that:</p> <p>a. one package of opened "Red Dot" electrodes expired 4/1999</p> <p>b. one unopened package of "Red Dot" electrodes had expired 11/2008</p> <p>c. 4 20 gauge IV (intravenous) catheters that expired 8/2012</p>			

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S1168	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iii)</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>(iii) Appropriate records must be kept pertaining to equipment maintenance, repairs, and electrical current leakage checks and analyzed at least triennially.</p> <p>Based on document review and interview, the center lacked documentation of preventive maintenance (PM) records on its patient care equipment in use at the center for 5 equipment.</p> <p>Findings:</p> <p>1. On 11-26-12 at 1215 hours, staff A1 was requested to provide documentation of PM for a nurse emergency call system, wheelchairs, patient carts, operating room (OR) tables and OR lights and none was provided prior to exit.</p>	S1168	The Director will be responsible. The nurse call system had the PM completed on 12/3/12. Digital Communications was called to do the PM. This was added to Contract monitoring spreadsheet developed that they need to be called annually by the center to have the PM completed. The wheelchairs and stretchers are now set up with Hill Rom to have annual PMs completed. Hill Rom signed PM contract on 12/12/12 to do the annual PMs for all stretchers and wheelchairs. They do the first PM in January 2013. The OR lights and one OR table are currently on	12/17/2012			

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	<p>2. The policy/procedure Emergency Nurse Call System (reviewed 12-11) indicated the following: " Annual PM and testing will be performed by (CS 4). "</p> <p>3. Center documentation indicated that the contracted service (CS 4) provided nurse call system testing and PM on 6-03-11.</p> <p>4. During an interview on 11-28-12 at 1410 hours, staff A1 confirmed that documentation of recent PM for the nurse call system and patient wheelchairs, carts, OR tables and Or Lights was not available.</p>		<p>the PM contract with Steris. They have been completing these PMs regularly. The documentation was not available at the time of the survey as the Director discovered after the survey when talking to some of the staff memebers that these reports go to one of the Surgical Techs and she has a book of these reports in the OR suite. Upon reviewing the documents, there was a PM for OR lights and one OR table completed however the report was not available at the time of the survey. The Director reviewed renewal contract with Steris to make sure the OR table and OR lights were on the contract on going as well. She met with the Surgical Tech and informed her that these documents need to be kept up to date and maintained. Director and Surgical Tech organized the binder to seperate the sterilizers, OR bed, OR lights reports. Called Didage Sales to see if they can do the PM on the 2nd OR table as Steris will not due to age and manufacturer (not Steris). Didage Sales will do the PMs for 2nd OR table and will be here in January 2013 to do the PM.</p>		

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S1170	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(b)(4)(B)(iv)</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>(iv) Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.</p> <p>Based on document review, observation and interview, the center failed to follow its policy/procedure and ensure that defibrillator inspection and testing was performed as recommended by the manufacturer.</p> <p>Findings:</p> <p>1. The Phillips M4735A HeartStart XL Defibrillator/Monitor (2006) Instructions for Use indicated the following: " perform a Shift/System Check ...along with visual inspection of the device and all cables, controls, accessories and</p>	S1170	The Director will be responsible. Policy (Testing and Care of Defibrillator) was revised/written specific for Phillips M4735A HeartStart equipment. Director met with staff person (Amanda) who does the daily checks. She was provided the new policy/procedure to review. She was asked to maintain the strips from the testing which also include the check off items required by the manufacture for proper checking of the equipment. Documentation was changed in daily log book to reflect the new policy/procedure.This became	12/17/2012
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	<p>supplies. Also regularly check expiration dates of all supplies, such as multifunction defib electrode pads ... "</p> <p>2. The policy/procedure Check of Emergency Equipment (approved 12-11) indicated the following: " The defibrillator check shall be performed in accordance with the manufacturer ' s directions at the beginning of the day. " The policy/procedure failed to indicate the following: A. perform a visual inspection of the device (page 11-6) B. additional checks indicated on the monitor report printout (example page 11-5) C. additional checks per manufacturer ' s recommendations (page 11-6).</p> <p>3. During a facility tour on 11-27-12 at 1600 hours, the center defibrillator Phillips M4735A was observed on the top of the Crash Cart with the document Crash Cart Defibrillator Check Sheet. The check sheet documentation failed to indicate the recommended checks listed in Section 11 Maintaining the HeartStart XL Equipment and a list of recommended checks to be performed was not observed elsewhere on the Crash Cart.</p> <p>4. During an interview on 11-27-12 at 1610 hours, staff A1 reviewed the</p>		effective January 1, 2013.	

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	operator ' s manual for the Phillips M4735A defibrillator and confirmed that the daily defibrillator checks were not being performed according to the manufacturer's recommendations.			

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S1182	<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>(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 lacked documentation of a functioning safety management program that collected and evaluated information about safety practices and hazards.</p> <p>Findings:</p> <p>1. The Quality Assurance [QA] Program (approved 11-12) indicated the following: " The QA committee receives and reviews all committee reports and minutes including ...safety, fire and disaster activities. " The QA program description failed to indicate the safety functions to be performed and reviewed by the QA committee.</p> <p>2. Review of governing board meeting minutes dated 12-19-11 and 3-27-12 failed to indicate participation by committee members or recommendations in response to identified safety concerns</p>	S1182	<p>The QA program will go under review by the Director and QA committee. The QA program/ plan will need to have safety as an integral portion of the plan. The safety and risk measures and/or concerns need to be reported to the Board quarterly. This includes sharp injuries, med errors, incident reports, emergency drills completed and response to drill. The Safety program will be incorporated into the QAPI program. A safety audit/rounding will be completed at a minimum of quarterly and as much as monthly. The QA committee will decide on frequency of the safety audit/rounding. This report will be provided to the Board quarterly.</p>	01/31/2013			

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	<p>or events. The 3-27-12 minutes indicated that a monthly Safety and Risk Management checklist was ongoing.</p> <p>3. Documentation of monthly Safety and Risk Management checklists dated 1-17-12, 2-10-12, 3-23-12 and 4-17-12 was provided by staff A2 upon request. Staff A2 was requested to provide documentation of all additional checks performed in 2012 and none was provided prior to exit.</p> <p>4. During an interview on 11-27-12 at 1430 hours, staff A2 confirmed that no additional safety rounding had been performed in 2012 and no additional documentation was available.</p> <p>5. Review of governing board meeting agenda dated 11-07-12 indicated no incident reports or sharps or work-related injuries for 2nd quarter 2012 and center Incident Report documentation indicated that 2 puncture injuries and a medication error occurred during the period.</p> <p>6. During an interview on 11-28-12 at 1030 hours, staff A1 confirmed that the center lacked documentation of an active safety management program.</p>			

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S1188	<p>410 IAC 15-2.5-7 PHYSICAL PLANT, EQUIPMENT MAINTENANCE, 410 IAC 15-2.5-7(c)(4)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(4) A written fire control plan that contains provisions for the following:</p> <p>(A) Prompt reporting of fires. (B) Extinguishing of fires. (C) Protection of patients, personnel, and guests. (D) Evacuation. (E) Cooperation with firefighting authorities. (F) Fire drills.</p> <p>Based on document review and interview, the center failed to maintain its fire control plan and maintain documentation of quarterly drill participation by center staff for 2 of 4 quarters.</p> <p>Findings:</p> <p>1. The policy/procedure Fire - Code F (approved 12-11) indicated the following: " Alert the staff of the fire by using the intercom ...[and] ...a test of the fire plan will be held at least once a quarter. "</p> <p>2. During an interview on 11-28-12 at 1050 hours, staff A1 confirmed that the center did not have an intercom for announcing a fire alert in the center and</p>	S1188	<p>The Director will be responsible with assistance from the Safety Office. The QA committee will review/revise the Fire Policies. The notation regarding an intercom is used will be revised to note phone system as there is not an active intercom system in the facility. Quarterly fire drills are performed and staff do participate in these. Documentation of staff participation is lacking however. The Director and or designee for the Fire Drill will make sure staff sign in for their participation when Fire Drills are conducted and participation log will be kept with the fire drill information.</p>	01/31/2013			

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	<p>confirmed that the policy/procedure had not been maintained.</p> <p>3. Documentation of a fire drill conducted at the medical office building (MOB) by the Lutheran Health Security department dated 10-16-12 lacked a staff roster indicating that center staff had participated in the drill activity.</p> <p>4. Documentation of a fire drill conducted at the MOB on 5-16-12 failed to indicate that center staff had participated in the drill activity.</p> <p>5. During an interview on 11-27-12 at 1430 hours, staff A2 confirmed that the documentation failed to indicate center staff participation in the fire drill activity for the 2 quarterly drills.</p>				