

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150112	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 12/01/2011
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NAME OF PROVIDER OR SUPPLIER COLUMBUS REGIONAL HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 2400 E 17TH ST COLUMBUS, IN47201
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S0000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 005099</p> <p>Dates: 11-29-11 through 12-1-11</p> <p>Surveyors:</p> <p>Billie Jo Fritch, RN, BSN, MBA Public Health Nurse Surveyor</p> <p>Ken Zeigler Laboratory Surveyor</p> <p>Deborah Franco, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 12/12/11</p>	S0000		
S0556	<p>410 IAC 15-1.5-2(b)</p> <p>(b) There shall be an active, effective, and written hospital-wide infection control program. Included in this program shall be system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.</p>			

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

TITLE

(X6) DATE

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

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	<p>Based on document review, observation and interview, the facility failed to have an effective infection control program to prevent the spread of communicable diseases in patients and health care workers for 61 of 66 employees (B#21-31, K# 1-20, D#1-18 and P1-18) and failed to assure reliable documentation that duration time for high level disinfection (HLD) and appropriate rinse cycles were achieved in 2 of 2 HLD areas observed.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. Review of personnel files on 11-29-11 through 12-1-11 indicated 41 of 48 staff members (B# 21 - 31, K #1 - 16, K# 19-20, and D#1 - 5, D#7 - 8, D#10 - 11, D#13 - 15, and D#17) lacked documented proof of immunity to Varicella.</li> <li>2. Review of personnel files on 11-29-11 through 12-1-11 indicated 48 of 48 staff members (B#21-31, K# 1-20, and D#1-18) lacked evidence of any ongoing/active surveillance of the onset of tuberculosis (TB)symptoms during 2011.</li> <li>3. Review of facility policy 6-659, titled TUBERCULOSIS TESTING AND SURVEILLANCE, approved 1-26-11 indicated the following: All employees, including those with a history of positive TST, will be notified annually of the need to be evaluated promptly for any</li> </ol>	S0556	<p>Tag # S 05561. How are you going to correct the deficiency?</p> <p>1.a. Varicella antibody titer screening will be performed on all employees without documentation of two doses of varicella vaccine or laboratory proof-of-immunity with those found to not be immune to start varicella vaccination. 1.b. A "Tuberculosis Screening" tool was sent to all employees on 12/15/11 requiring employee to complete, sign, and return the screening tool to Employee Health by 12/29/11. 1.c. On 12/14/11 Infection Control designated "high-risk" departments (Emergency Department, Critical Care Unit, 6 Tower Medical Surgical Unit, Endoscopy, Respiratory Care, Lung Center, Microbiology and Ambulance Service) for acquisition of TB infection/disease. Employees of these departments will have a TST placed no later than December 29, 2011 and will be required to have a TST annually thereafter. 1.d. Policy for High-level disinfection with OPA has been revised (12/14/11) to require documentation of time device placed and removed from disinfectant solution and completion of three (3) rinse cycles. Logs for high-level disinfection of patient care items with OPA were also revised to include time device placed and removed from disinfectant</p>	12/29/2011

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	<p>pulmonary symptoms suggestive of TB, e.g. bloody sputum or persistent cough greater than two weeks duration.</p> <p>4. Interview with #B15 on 11-29-11 at 1545 hours confirmed the facility's infection control program does not require documented proof of immunity to varicella and does not ensure those without documented, reliable proof of immunity to varicella are prevented from working during a community outbreak of varicella in order to prevent the spread of communicable diseases to patients or other health care workers.</p> <p>5. Interview with B#15 on 11-10-11 at 0935 hours indicated the facility has not notified/educated employees during 2011 to be evaluated for the symptoms of TB or completed active or on-going surveillance to determine whether an employee is experiencing symptoms of TB; B#15 indicated the infection control committee determined none of the hospital departments, including respiratory therapy, emergency department, lung center, and laboratory, are at a higher risk of contracting TB and determined no employees in specific units would require annual skin testing for TB.</p> <p>6. At 2:20 PM on 11/30/2011 review of personnel files indicated:</p> <p>a. staff members P1-5, P7, P8, P10, P11, P13-15, and P17 had only self-reported Varicella immunity.</p>		<p>solution, and completion of 3 rinse cycles.2. How are you going to prevent the deficiency from recurring in the future? 2.a. Current policy is that new hires without documentation of two doses of varicella vaccine or laboratory proof-of-immunity are required to have a varicella antibody titer drawn and if found to not be immune, are required to take varicella vaccine. A monthly schedule (200 by January 31, 2012; 200 - 300 each subsequent month i.e. 200 - 300 by February 29, 2012; 200 - 300 by March 31, 2012; 200 - 300 by April 30, 2012; 200 - 300 by May 31, 2012 ; 200 - 300 by June 30, 2012) for going back and capturing employees without this documentation of varicella vaccine will be implemented with full compliance to be accomplished by June 30, 2012. 2.b. Mandatory annual infection control inservice program for 2012 will be revised to include a section instructing employees on the need to be evaluated promptly for any pulmonary symptoms suggestive of TB disease. A daily report (sent to Infection Control and Employee Health) will be generated identifying any employees reporting symptoms from the screening questions. Employees are required to complete mandatory annual infetion control inservicing with failure to do so resulting in work stoppage. 2.c. Employees in</p>		

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	<p>b. staff members P1-18 lacked annual PPD skin tests or an annual TB risk assessment. 7. During interview with S9 on 11-30-2011 at 2:20 PM, S9 verified the above.</p> <p>8. Facility policy "High-Level Disinfection of Patient Care Items with Ortho-Phthalaldehyde" last reviewed/revised 07/2011, states in pertinent part on Page 2, #3 High-Level Disinfection "Immerse device completely, filling all lumens and eliminating air pockets, in solution for a minimum of 12 minutes at 20 degrees C or higher to destroy all pathogenic microorganisms. Remove device from solution and rinse thoroughly following the rinsing instructions below" and on Page 2, #4 Rinsing Instructions (Potable tap water) a. Following immersion in solution, thoroughly rinse the device by immersing it completely in a large volume (e.g., 2 gallons) of water or placing under running water for at least 1 minute assuring that all areas touched by disinfectant are completely rinsed. b. Repeat this procedure twice. Use volumes of fresh water when rinsing by immersion. c. Each rinse should be a minimum of 1 minute in duration unless otherwise noted by the device or equipment manufacturer".</p> <p>9. The manufacturer's instructions for use of MetriCide OPA Plus (a</p>		<p>designated "high risk" areas will be required to have a TST on an annual basis with failure to do so resulting in work stoppage. 2.d. High-level disinfection log revision will be reviewed with staff that does high-level disinfection with OPA and logs will be reviewed for completeness and appropriateness by Infection Preventionist on a monthly basis.3. Who is going to be responsible for numbers 1 and 2 above? 3.a Employee Health Nurse 3.b. Employee Health Nurse 3.c. Employee Health Nurse 3.d. Infection Preventionist4. By what date are going to have the deficiency corrected? 4.a. December 29, 2011 with plan (in 30 day increments) for completion of screening by June 30, 2012. 4.b. December 29, 2012 4.c. December 29, 2012 4.d. December 29, 2012</p>				

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	ortho-Phthalaldehyde solution) provide in pertinent part "Manual Processing. High Level Disinfectant at a minimum of 20 degrees Celsius (68 degrees Fahrenheit). MetriCide OPS Plus Solution is a high level disenfectant when used or reused, according to the Directions for Use, at or above its Mimimum Recommended Concentration (MRC) as determined by MetriCide OPA Plus Test Strips, with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days. Remove the device from the solution and rinse thoroughly with sterile water or potable tap water. Repeat the procedure TWO (2) additional times, for a total of THREE (3)RINSES, with large volumes of fresh water, at least 9 liters each, to remove MetriCide OPA Plus Solution residues. Residues may cause serious side effects. SEE WARNINGS. THREE (3) SEPARATE , LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED, THE VOLUME OF WATER USED IN EACH RINSE CYCLE SHOULD BE AT LEAST 9 LITERS" (capitalization in original) and under C. Special Instructions for Transesophageal Echocardiography (TEE) probe reprocessing "Soaking for 12 minutes in MetriCide OPA Plus Solution is required for high level disinfection (HLD). Excessive soaking of the probes (e.g., longer than an hour) during HLD			

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	<p>and/or not rinsing three times with a fresh quantity of water each time as described in part B, may result in residual MetriCide OPA Plus Solution remaining on the device, the use of which may cause staining, irritation or chemical burns of the mouth, throat, esophagus and stomach".</p> <p>10. During tour of the facility on 11-29-2011:</p> <p>a. At 11:00 AM in the Surgical Services Department, the log of High Level Disinfection was inspected and showed the log lacked documentation of the time device was removed from Metricide Solution or the completion of 3 rinse cycles which are required to be performed by the facility policy and manufacturer's instructions.</p> <p>b. At 3:00 PM on 2Tower during inspection of soiled utility room the High Level Disinfection log lacked documentation of the time device was removed from the solution or the completion of 3 rinse cycles which are required to be performed by facility policy and manufacturer's instructions.</p> <p>11. During interview with S21 on 11-29-2011 at 11:05 AM, S21 stated:</p> <p>a. MetriCide OPA Plus Solution is used for High Level Disinfection of non-autoclavable devices such as laryngoscope blades, glidescope, stylets, and endoscopic dilators.</p>				

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	<p>b. The log of high-level disinfection is copied and sent to the Infection Control Officer monthly for review.</p> <p>c. It cannot be determined by examination of the log that immersion time in the solution met the minimum immersion time and rinse cycles which are required by facility policy and manufacturer's instructions.</p> <p>12. During interview with S22 on 11-29-2011 at 3:05 PM, S22 stated:</p> <p>a. The wall mounted tube stations in the soiled utility room on 2Tower are used for High Level Disinfection exclusively of the TEE probe used by Cardiac Sonographers (CS).</p> <p>b. When the probe is immersed in Metricide OPA Plus solution in the utility room, the ultrasonographers often return to the office or complete other duties.</p> <p>c. The ultrasonographers record the time that the TEE probe began its high level disinfection cycle. While the TEE probe is in MetiCide OPA Plus solution, other duties such as telephone calls may interrupt the ability of the CS to remove the TEE probe promptly after attaining the 12 minute minimum high disinfectant cycle.</p> <p>d. The time the TEE probe is in solution can vary. The minimum time of 12 minutes is observed, however the TEE probe may be solution longer than 12 minutes. No matter how long the probe</p>				

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	<p>has been in solution; the practice is to rinse the TEE probe 3 times in tap water.</p> <p>e. The log of high-level disinfection is copied and sent to the Infection Control Officer monthly for review.</p> <p>13. During interview with S4 on 12/1/2011 at 9:45 AM, S4 stated:</p> <p>a. Facility policy does not require time removed from solution or completion of 3 rinse cycles to be documented on the HLD log.</p> <p>b. The current High Level Disinfection logs used in Surgery and on 2Tower do not provide the end time of the disinfection cycle or documentation that rinse cycles have been performed per facility policy and manufacturer's recommendations.</p> <p>c. It cannot be reliably determined that the minimum time of 12 minutes for High Level Disinfection has been achieved if the end time of the disinfection cycle cannot be determined.</p> <p>d. It cannot be reliably determined that three (3) rinse cycles have been performed as per facility policy and manufacturer's recommendation without documentation of the rinse cycles on the log.</p> <p>e. There may be instances when additional rinse cycles are required per the MetriCide OPA Plus Instructions for Use and the current documentation does not provide sufficient evidence upon which to make such determinations.</p>						

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S0952	<p>410 IAC 15-1.5-6(d)</p> <p>(d) Blood transfusions and intravenous medications shall be administered in accordance with state law and approved medical staff policies and procedures. If the blood transfusions and intravenous medications are administered by personnel other than physicians, the personnel shall have special training for these procedures in accordance with subsection (b)(6). Based on blood transfusion policy review, transfusion document chart reviews and staff interview, the hospital failed to administer blood transfusions in accordance with approved medical staff policies and procedure for three of twenty-five patients.</p>	S0952	<p>Tag S 09521. How are you going to correct the deficiency? a. Temperature increase of greater than 2 degrees Fahrenheit during blood transfusion i. Policy PC-B-1 00005 revised to include "Exception: In case of hypothermia (the classification of Mild Hypothermia according to</p>	12/28/2011

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	<p>Findings include:</p> <p>1. The policy, "Transfusion Reaction, Suspected", Policy/Procedure Code: PC-B-1 00005 r6-0, revised 6/07/10, read: "Special Instruction:</p> <p>1. Possible transfusion reactions symptoms: Fever increase of greater than 2 degrees Fahrenheit (F) from baseline Procedure</p> <p>1. Stop blood infusion immediately. 2. The transfusion set is disconnected... 3. Check vital signs 4. Call the patient's physician and relay patient's symptoms. 5. The blood bags, tubings and filters are saved in a zip-close bag 6. Reverify Blood Bank Transfusion Tag, unit of blood, and patient identification band for agreement of: a blood group and Rh type, b. patient identification numbers 7. Complete nursing form "Report of Suspected Transfusion Complication" 8. Call Blood Bank 9. A urine same is collected... 10. Document above in Medical Record."</p> <p>2. The policy, "Blood: Packed Cells, Fresh Frozen Plasma Transfusion", Policy/Procedure Code: PC-B-1 000007 t10-0, revised 7/29/10, read: "Record fifteen minute vital signs on the</p>		<p>Fundamentals of Nursing, Potter &amp; Perry 6th Edition is 93.2 - 96.8 degrees Fahrenheit) since a temperature increase is expected, monitor closely for other signs of transfusion reaction and act accordingly." to align with the Technical Manual, 17th Edition, American Association of Blood Banks 2011, Clinical Practice of Transfusion Medicine 1996 and Fundamentals of Nursing 6th Edition. ii. Obtained policy change approval by the Medical Director of the Blood Bank iii. Policy revision to be presented at Nurse Practice Council. iv. Memo to Nurse Managers and RN staff informing them of revision of the policy and the expected reporting of a potential transfusion reaction according to policy.b. Vital signs not documented on transfusion tagi. Memo to Nurse Managers and RN staff informing them of documentation requirements for transfusion tags. 2. How are you going to prevent the deficiency from recurring in the future? a.i.) Review transfusion tags for compliance with policy for temperature increase of more than 2 degrees Fahrenheit and report patterns and trends to Nursing Leadership Forum for quarterly reporting, recommendations and action plan.a.ii. Add to Health Streams e-learning module for all RNs a</p>		

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	<p>Transfusionist TAG"</p> <p>2. In review of twenty-five patients receiving blood units, three of these received-units did not have complete documentation on the Crossmatch Transfusion Tag sheet including:</p> <p>Patient #3 -Unit administered on 11/01/11 at 1410, with the patient's temperature at 97.2 degrees F and a temperature of 99.4 degrees F at 1425 (this was a 2.2 degree F temperature elevation) with no documentation, indicating action(s) had been taken for a transfusion reaction, available for review in the patient's chart. This same unit was listed as issued from the blood bank at 1415 and started at 1410.</p> <p>Patient #13 -Unit administered on 10/28/11 at 1200, had documentation in its 15 minute vital temperature as '54' (the pulse, located immediately above this blank was 57).</p> <p>Patient #16 -Unit administered on 10/26/11 at 0910, with the patient's 15 minute temperature reading at 0925 of 94.5 degrees F and a temperature of 97.0 degrees F at 1050 (this was a 2.5 degree F temperature</p>		<p>check off for policy PC-B-1 00005 that includes reporting of possible transfusion reaction. b.i.) Review transfusion tags for complainece with policy for documentation of vital signs and report patterns and trends to Nursing Leadership Forum for quarterly reporting, recommendations and action plan.b.ii.) Add to Health Streams e-learning module for all RNs a check off for transfusion tag completion.3. Who is going to be responsible for numbers 1 and 2?1.a.i.) Manager of Clinical Laboratory Services1.a.ii.) Manager of Clinical Laboratory Services1.a.iii) Director of Nursing1.a.iv.) Director of Nursing1.b.i.) Director of Nursing2.a.i.) Manager of Clinical Laboratory Services2.a.ii.) Director of Nursing2.b.i.) Manager of Clinical Laboratory Services2b.ii.) Director of Nursing4. By what date are you going to have the deficiency corrected?1.a.i..) 12/20/2011 Policy revision completed 1.a.ii.) 12/20/2011 Policy approved by Medical Director of Blood Bank 1.a.iii.) 01/11//2012 Present to Nurse Practice Council 1.a.iv.) 12/28/2011 Memo to Nurse Managers and Nursing Staff 1.b.i.) 12/28/2011 Memo to Nurse Managers and RN staff 2.a.i.) 02/2012 Review transfusion tags for temperature complainece with policy for temperature increase of more than 2 degrees Fahrenheit and</p>		

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S1164	<p>elevation) with no documentation, indicating action(s) had been taken for a transfusion reaction, available for review in the patient's chart</p> <p>3. On 11/31/11 at 10:45 a.m., staff member #3 acknowledged the above-listed missing documentation including that these patients had received blood without benefit of properly completed documentation, and that their respective vitals were not assessed, reported or completed per policy.</p> <p>410 IAC 15-1.5-8(d)(2)(B)</p> <p>(d) The equipment requirements are as follows: (2) There shall be sufficient equipment and space to assure the safe, effective, and timely provision of the available services to patients, as follows:  (B) There shall be evidence of preventive maintenance on all equipment. Based on observation, document review, and interview, the facility failed to perform and document daily preventative maintenance inspection and testing of its defibrillators in two (2) of eleven (11) patient care units.  Findings included:</p>	S1164	<p>report findings to Nursing Leadership Forum2.a.ii.) 02/27/2012 add e-learning module to Health Streams2.b.i.) 02/2011 Revoew transfusion tags for compliance with policy for documentation of vital signs and report findings to Nursing Leadership Forum.2.b.ii.) 02/27/2012 add e-learning module to Health Streams</p> <p>Tag # S11641. How are you going to correct the deficiency? Beginning Monday, December 5th, 2011, communication was shared with all Respiratory Care staff members regarding requirement to document code cart/defibrillator checks during their shift. An email communication was also sent to</p>	12/19/2011	

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NAME OF PROVIDER OR SUPPLIER  COLUMBUS REGIONAL HOSPITAL			STREET ADDRESS, CITY, STATE, ZIP CODE 2400 E 17TH ST COLUMBUS, IN47201		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
	<p>1. During tour of the Intensive Care Unit on 11/29/2011 at 2:00 PM the defibrillator log was observed lacking complete documentation of performance of daily maintenance on four (4) dates in November 2011 and on 2 dates in October 2011. The missing documentation concerned cart lock status, oxygen cylinder pressure check, plugged in status, presence of electrodes, presence of electrode cable connector, defibrillator functional test, and recorder function.</p> <p>2. During tour of the OB Unit on 11/29/2011 at 1:35 PM, the defibrillator log was observed lacking complete documentation of performance of daily maintenance on three (3) dates in November 2011, two (2) dates in August 2011, and eleven (11) dates in July 2011. The missing documentation concerned cart lock status, RT box sealed, oxygen cylinder pressure check, manual resuscitator, plugged in status, presence of electrodes, presence of electrode cable connector, defibrillator functional test, and recorder function.</p> <p>3. Facility policy "Defibrillator Checks (Zoll)/Code Cart Checks; Daily", last reviewed/revised 7/6/2009 states in pertinent part</p>		<p>staff reinforcing this expectation. The OB and CCU Code cart checks are also included in the Respiratory Therapist shift assignments. The Respiratory Therapist assigned to the CCU will have responsibility for checking the OB and CCU code cart/defibrillator. This will allow for a standardized process of checking and verifying defibrillator equipment. 2. How are you going to prevent the deficiency from recurring in the future? The Respiratory Care Coordinator will monitor for compliance on a daily basis. Communication will be given between shift reports if there has been any issue identified regarding the code cart/defibrillator checks. 3. Who is responsible for # 1 and #2? Respiratory Care Department Director 4. By what date are you going to have the deficiency corrected? Changes have been implemented effective week of December 5, 2011. As of 12/19/2011, the Respiratory Therapists will assume responsibility for checking and inspecting defibrillators in the CCU area. As of 12/19/2011, we are at 100% compliance for defibrillator checks in both OB and CCU.</p>		

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	<p>a. On Page 1, "2.b. Check the code cart in accordance with the Code Cart Check Sheet (front and back), back of the checksheet verifying completion (includes lock integrity and defib functionality).</p> <p>b. On Page 2 "1. Code cart checks will be completed daily".</p> <p>c. On Page 3 Procedure for Code Cart Checks "1. Once each calendar day, the locked cart will be checked for integrity (RT or unit designee will perform). 2. Check sheet will be signed after each check has been completed".</p> <p>4. During interview with S4 on 12-1-2011 at 9:45 AM S4 verified the above and stated:</p> <p>a. Missing or incomplete documentation of the crash cart check off sheet is a violation of facility policy and of manufacturer's instructions for use.</p> <p>b. Without complete accurate documentation of the daily maintenance checks of the crash cart and defibrillators, it cannot be determined that the crash carts and defibrillators are ready and safe for patient use.</p> <p>c. A census of zero is not an exception to the facility policy or the manufacturer's guidelines for daily testing of the crash cart and defibrillator.</p>				

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