

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150075	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 04/02/2014
NAME OF PROVIDER OR SUPPLIER BLUFFTON REGIONAL MEDICAL CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 303 S MAIN ST BLUFFTON, IN 46714		
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S000000	<p>This visit was for a State hospital licensure survey.</p> <p>Dates: 3/31/2014 through 4/2/2014</p> <p>Facility Number: 005069</p> <p>Surveyors: Albert Daeger, CFM, SFPIO Medical Surveyor</p> <p>Saundra Nolfi, RN PH Nurse Surveyor</p> <p>QA: claughlin 04/07/14</p>	S000000	N/A		

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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S000596	<p>410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(iii)</p> <p>(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (3) The infection control committee responsibilities shall include, but not be limited to, the following: (D) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(iii) Cleaning, disinfection, and sterilization.</p> <p>Based on observation, documentation review, and staff interview, the facility failed to ensure chemical Cidex OPA was used according to the manufacturer's recommendations and hospital policies.</p> <p>Findings included:</p> <p>1. The hospital was using Ortho-phthalaldehyde Solution (Cidex OPA), high level disinfectant for semi-critical devices. Cidex OPA manufacturer sheet requires: Manual processing -</p>	S000596	The Infection Control Preventionist is responsible for compliance with Infection control processes. The radiology director, infection control nurse, and quality director met to revise the Bluffton Regional Medical Center Use of Cidex Policy #US-32 to include: A separate container will be filled with 2 gallons water, device will be immersed for 1 minute. Remove device from container, empty, refill with 2 gallons water, immerse device for 1 minute. Rinsing process repeated for 3 cycles of 1 minute immersion in 2 gallons of water. Thorough rinsing is important, as residual Cidex OPA can irritate mucous membranes of patients. Use a minimum of 3 (three) large volume immersion rinses. Do not re-use rinse water. . The revised	05/06/2014			

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	<p>Immerge device completely, filling all lumens and eliminating air pockets in Cidex OPA solution for a minimum of 12 minutes at 68 degrees F or higher; Manual rinsing procedure - thoroughly rinse the semi-critical medical device by immerging it completely in 2 gallons of water 3 times. Each time should be done for a minimum of 1 minute. Always use fresh water each time this step is done.</p> <p>2. Bluffton Regional Medical Center Use of Cidex policy #US-32 (Last reviewed 9/12) stated, "Follow the manufacturer guidelines."</p> <p>3. At 1:45 PM on 4/1/2014, staff member #16 explained how he/she rinses the vaginal probes after they have been submerged into Cidex OPA for 12 minutes. The Cidex room has 1 covered container for the Cidex OPA and 1 container for the rinsing of the probes. The staff member indicated he/she places the probe in the container and pours</p>		<p>Cidex policy will be reviewed and approved at Infection control committe. All staff that use OPA – Cidex will be re-educated to the revised policy and will have competency validated The radiology director will educate the staff and document competency of Cidex rinsing. 100% of staff training and competency will be verified and audited for completeness. Audit results will be reported to the Infection Control Committee and quality council.</p>	
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	<p>onto the probe a 1-gallon pitcher of water 3 separate times without changing the water between the pouring steps.</p> <p>4. At 11:15 AM on 4/2/2014, staff member #2 confirmed the rinsing procedure that was done by staff member #16 on 4/1/2014 did not comply with the manufacturer's requirements for rinsing procedures of Cidex OPA.</p>			
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S000726	<p>410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4 (c)(7)(A)(B)</p> <p>(c) An adequate medical record shall be maintained with documentation of service rendered for each individual who is evaluated or treated as follows:</p> <p>(7) The hospital shall ensure the confidentiality of patient records which includes, but is not limited to, the following:</p> <p>(A) A procedure for releasing information from or copies of records only to authorized individuals in accordance with federal and state laws.</p> <p>(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.</p> <p>Based on observation and interview, the facility failed to protect patient medical records from unauthorized access in the Rehab Unit of the South Campus.</p> <p>Findings included:</p> <p>1. During the tour of the Rehab Unit of the South Campus at 1:30 PM on 04/01/14, accompanied by staff members A1 and A14, patient medical records were observed stored on open shelves in the Physical Therapy office.</p> <p>2. At 1:30 PM on 04/01/14, staff</p>	S000726	<p>The Compliance Officer is responsible for education and compliance ensuring authorized access to patients medical records. The patient medical records are now placed in a locked file cabinet in the Physical Therapy (PT) office when the records are in the office for documentation or use. 100% of the Physical Therapy department staff were educated to the revised process for locking medical records when not in use. The Quality Director will conduct monthly rounds in the PT area for 3 consecutive months to ensure all records are secured. Results will be</p>	05/06/2014			

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	<p>member A14 indicated the office was locked when staff was not present; however, he/she acknowledged the housekeeping staff had a key to the office and might clean in the office before staff arrived.</p> <p>3. At 2:30 PM on 04/01/14, staff member A1 indicated he/she talked with the environmental services director, A21, who confirmed the staff started cleaning the South Campus at 6:00 AM and could be in the office without any Rehab staff present.</p>		<p>reported to the Patient Care Review (Medical Records) Committee.</p>	

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S000748	<p>410 IAC 15-1.5-4 MEDICAL RECORD SERVICES 410 IAC 15-1.5-4 (e)(3)</p> <p>(e) All entries in the medical record shall be:</p> <p>(3) authenticated and dated promptly in accordance with subsection (c)(3). Based on policy review, medical record review, and interview, the facility failed to ensure all medical record entries were authenticated and dated according to policy for 2 of 5 patient consents for blood transfusions (#N1 and N2) and for 5 of 16 discharge summaries of hospitalized patients (#N3, N10, N11, N14, and 15).</p> <p>Findings included:</p> <p>1. The facility policy "Medical Record Entries", last reviewed 10/11, indicated, "All entries within the patient's health information record (medical record) must be accurate, complete, legible, dated, timed, and authenticated."</p> <p>2. The facility policy "Delinquent Record", last reviewed 11/10, indicated, "Bluffton Regional Medical Staff Operating Policy has defined a delinquent record as any record that remains incomplete thirty days after the patient's discharge."</p>	S000748	<p>The Chief Medical Officer is responsible for medical staff oversight and provided physician education on documentation including dating, timing, and and timeliness of discharge summary requirements as outlined in the Medical staff Rules and Regulation and hospital policy. Medical Staff education was conducted by memo communication from the CMO to the medical staff on April 17, 2014 Measures to prevent reoccurrence. The HIMS Manager will random audits of surgical and blood transfusion consents forms to verify completeness including date and time. 30 records will be sampled monthly for 3 consecutive months. Results will be reported to the Quality Council and Medical Executive Committee. The HIMS Manager will conduct monthly monitoring of discharge summaries for 3 consecutive months or compliance with completeness of discharge summaries for a minimum of 90 % compliance is met for 3 consecutive months. Findings will be presented to Quality</p>	05/01/2014			

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	<p>3. The medical record for patient #N1, a 94-year old admitted 10/09/13, who received blood transfusions on 10/10/13 and 10/11/13, indicated a form "Transfusion of Blood & Blood Components Consent/Refusal" that was signed by the patient and a witness, but without any dates or times for the signatures.</p> <p>4. The medical record for patient #N2, a 61-year old admitted 01/17/14, who received blood transfusions on 01/17/14, indicated a form "Transfusion of Blood & Blood Components Consent/Refusal" that was signed by the patient and a witness, but the patient's signature was on the line for the physician. The patient indicated a date, but no time, and the signature for the witness lacked both a date and a time.</p> <p>5. The medical record for patient #N3, a 73-year old admitted 12/10/13 and expired 12/13/13, indicated a Discharge Summary dictated by the physician on 01/12/14, but not authenticated until 01/21/14, greater than 30 days after the death. The summary also indicated the patient was admitted to hospice care on December 12, 2013, but did not document the death.</p> <p>6. The medical record for patient #N10, an 88-year old admitted 01/11/14 and</p>		Council with reports forwarded to Medical Executive committee and Board of Trustees.		

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	<p>expired 01/14/14, indicated a Discharge Summary dictated by the physician on 02/16/14 and authenticated on 02/17/14, greater than 30 days after the death.</p> <p>7. The medical record for patient #N11, a 79-year old admitted 01/27/14 and transferred 01/29/14, indicated a Discharge Summary dictated by the physician on 03/09/14 and authenticated on 03/10/14, greater than 30 days after the transfer.</p> <p>8. The medical record for patient #N14, a 10-year old admitted 11/20/13 and discharged 11/24/13, indicated a Discharge Summary dictated by the physician on 01/17/14 and authenticated on 01/20/14, greater than 30 days after discharge.</p> <p>9. The medical record for patient #N15, a 12-year old admitted 11/02/13 and discharged 11/05/13, indicated a Discharge Summary dictated by the physician on 12/15/13 and authenticated on 12/17/13, greater than 30 days after discharge.</p> <p>10. At 11:30 AM on 04/02/14, staff members A1 and A22, who assisted with the electronic medical record review, confirmed the medical record findings and acknowledged the documentation</p>						

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S000952	<p>410 IAC 15-1.5-6 NURSING SERVICE 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 policy review, medical record review, and interview, the facility failed to ensure physician orders and policy were followed regarding blood transfusions for 2 of 5 patients receiving blood transfusions (#N4 and N5).</p> <p>Findings included:</p> <p>1. The facility policy "Blood Transfusion Procedure". last reviewed 01/14, indicated, "2. Blood should be transfused over a 2 to 3 hour period unless the physician orders blood transfused at a different rate."</p> <p>2. The medical record for patient #N4, a 73-year old admitted 11/05/13, indicated a physician order from 11/09/13 for 2 units of packed red blood cells, each unit to be transfused over 4 hours. The record indicated the first unit was started at 2155 on 11/09/13 and completed at 0030 on</p>	S000952	<p>The Chief Nursing Officer is responsible for compliance with nursing policies. All nursing staff will be reeducated by the Nursing Directors regarding compliance with physician orders for blood transfusions and verifying the completeness of transfusion consents. All staff re-education will be completed by May 1, 2014. The Blood Transfusion policy is under review by nursing and blood bank services. Any recommended revisions to the transfusion policy or procedure will presented at Patient Care Review and quality committee for approval on April 17, 2014. Measures to prevent reoccurrence. The nursing directors will provide an in-service to nursing staff on following orders for blood transfusion and completing transfusion consents. The in-service included the read and verify orders and consents prior to initiation of blood transfusion. The nursing</p>	05/01/2014			

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	<p>11/10/13, two hours and 35 minutes later. The second unit was started at 0140 on 11/10/13 and completed at 0520 on 11/10/13, three hours and 40 minutes later.</p> <p>3. The medical record for patient #N5, an 84-year old admitted 11/23/13, indicated a physician order from 11/23/13 for 2 units of packed red blood cells, each unit to be transfused over 4 hours. The record indicated the first unit was started at 2335 on 11/23/13 and completed at 0205 on 11/24/13, two hours and 30 minutes later. The second unit was started at 0235 on 11/24/13 and completed at 0506 on 11/24/13, two hours and 31 minutes later.</p> <p>4. At 10:00 AM on 04/02/14, staff members A2 and A22, who were reviewing the records on the electronic system, confirmed the transfusions were not given according to policy and physician orders.</p>		<p>directors will conduct monthly audits of blood transfusions for six months to verify 90% compliance is met. Findings will be presented to Quality Council with reports forwarded to Medical Executive committee and Board of Trustees.</p>		

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S000954	<p>410 IAC 15-1.5-6 NURSING SERVICE 410 IAC 15-1.5-6(e)</p> <p>(e) Emergency equipment and emergency drugs shall be available for use on all nursing units.</p> <p>Based on observation, facility document review, policy review, and interview, the facility failed to perform checks of emergency equipment and supplies to prevent outdated supplies in the surgical area.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. During the tour of the surgical area at 11:00 AM on 04/01/14, accompanied by staff member A11, the Malignant Hyperthermia cart was observed containing a Foley catheter tray with an expiration date of 11/13. The Difficult Airway cart was observed containing a size 4 LMA laryngoscope with an expiration date of 03/28/14 and an Introducer with an expiration date of 07/13. 2. A log sheet on top of the Malignant Hyperthermia cart indicated monthly checks of the cart were performed only through May of 2013, with a check mark by one item in the cart in July and one in November. The Difficult Airway cart lacked a log of any checks. 	S000954	<p>The Chief Nursing Officer is responsible for compliance with policies. The CNO and surgery director met to create a OR cart checking and cleaning policy. The OR cart checking and cleaning policy will be reviewed at the next Department of Surgery committee. Measures to prevent reoccurrence. The surgery director provided an in-service to surgery staff on the OR cart checking including all emergency carts in the OR areas for compliance with checking supply expiration dates, cleaning, and completion of the logs. The surgery director will conduct monthly auditing of program for six months or until 100% compliance is met. Findings will be presented to Quality Council with reports forwarded to Medical Executive committee and Board of Trustees.</p>	05/01/2014
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	<p>3. The facility policy "Emergency Cart/Defibrillator Checking and Cleaning", effective 12/27/13, indicated, "To provide guidelines for cleaning and checking of emergency carts and defibrillators throughout the facility in order to ensure complete and functioning emergency equipment. ...1. All emergency carts are to be checked one time daily. ...3. The following procedures and cleaning are completed one time per month. Record the cleaning on the emergency cart check off log. A. Check all supplies thoroughly."</p> <p>4. At 11:00 AM on 04/01/14, staff member A11 indicated it was the nurses' responsibility to check the emergency carts in the surgical area and he/she thought this was done monthly. He/she confirmed the log lacked documentation that this was done and acknowledged there were some expired items.</p> <p>5. At 10:30 AM on 04/02/14, staff members A1 and A2 indicated the policy provided actually referred to the emergency crash carts which were checked monthly by the sterile processing tech. Both staff members indicated there was not another policy to cover the other surgical emergency carts.</p>			
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S001028	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(E)</p> <p>(d) Written policies and procedures shall be developed and implemented that include the following:</p> <p>(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:</p> <p>(E) Security of and authorized access to all drug storage areas within the hospital, as approved by the medical staff, when the pharmacist is absent.</p> <p>Based on observation, documentation review, and staff interview, the facility failed to ensure all medications are secured while storing them in the Infectious Waste Room and failed to ensure medications were secured to prevent unauthorized access in the surgical department.</p> <p>Findings included:</p> <p>1. Bluffton Regional Medical Center Pharmaceutical Waste Disposal policy (Last reviewed 11/2011) stated, "The Pharmacy Department shall assume primary</p>	S001028	The Plant Operations Director is responsible for compliance with facility waste disposal polices. The Plant Operation Director, Quality Director and Pharmacy Director met and revised the process of storage in the infectious waste room. The pharmaceutical waste was placed in a locked cage with key assess limited to pharmacy personnel. All Plant Operations, and pharmacy staff were re-educated to the revised process. Re-education of staff completed on: May 6, 2014 Weekly rounds of the pharmacy will be conducted by the Director of Plant Operations or designee to verify compliance with revised process and proper disposal of pharmaceutical waste. Weekly rounds will be performed for 3 consecutive months and results will be reported to the Quality Council and to	05/06/2014			

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	<p>responsibility for properly receiving, handling, labeling and storing pharmaceuticals and hazardous drugs and oversight for the storage of pharmaceuticals.</p> <p>2. At 12:45 PM on 4/1/2014, the Infectious Waste Storage Room was toured. The room contained red biohazard containers toward the front of the room. In the rear of the room was four 55-gallon blue plastic covered drums marked with either hazardous material or no-hazardous material. The opposite side of the drums were blue and black unsecured covered containers of partially used assorted medications in the two containers (medication vials, medication IV bags, etc...). The medication in the room was unsecured from access of non-essential personnel.</p> <p>3. At 1:00 PM on 4/1/2014, staff member #21 indicated the discarded medication in the black and blue containers is emptied into</p>		<p>Medical Executive committee and Board of Trustees. The surgery director is responsible for compliance with medication security on carts. The surgery director re-educated anesthesia staff regarding anesthesia cart security of medication and supplies. The OB director educated all nursing staff on infant warmer security of cart and medication. . Measures to prevent reoccurrence. The surgery director will conduct weekly observations for anesthesia cart and infant warmer being locked for 3months consecutive months or until 100% compliance is met. Findings will be presented to Quality Council with reports forwarded to Medical Executive committee and Board of Trustees.</p>	

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	<p>the appropriate 55-gallon blue plastic drum by removing the plastic liner filled with assorted pharmaceuticals and dropping it into the large containers for the biohazard haulers to collect.</p> <p>4. At 1:30 PM on 4/2/2014, staff member #24 confirmed there was a medication security concern with the handling and storing medication in the Infectious Wasting Handling Room.</p>			
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S001028	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(E)</p> <p>(d) Written policies and procedures shall be developed and implemented that include the following:</p> <p>(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:</p> <p>(E) Security of and authorized access to all drug storage areas within the hospital, as approved by the medical staff, when the pharmacist is absent.</p> <p>5. During the tour of Endoscopy Room 1, which was unoccupied, at 10:35 AM on 04/01/14, accompanied by staff member A11, the anesthesia cart was observed unsecured. A drawer of the cart contained a tray of various vials of medication.</p> <p>6. During the tour of OR (operating room) 1 at 10:50 AM on 04/01/14, accompanied by staff member A11, the Kreiselman (infant warmer) was observed unsecured. A drawer of the warmer contained various vials of medication; Epinephrine, Sodium</p>	S001028	<p>The Plant Operations Director is responsible for compliance with facility waste disposal polices. The Plant Operation Director, Quality Director and Pharmacy Director met and revised the process of storage in the infectious waste room. The pharmaceutical waste was placed in a locked cage with key assess limited to pharmacy personnel. All Plant Operations, and pharmacy staff were re-educated to the revised process. Re-education of staff completed on: May 6, 2014 Weekly rounds of the pharmacy will be conducted by the Director of Plant Operations or designee to verify compliance with revised process and proper disposal of pharmaceutical waste. Weekly rounds will be performed for 3 consecutive months and results will be reported to the Quality Council and to</p>	05/06/2014			

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	<p>Bicarbonate, Atropine. and Calcium Gluconate.</p> <p>7. At 11:00 AM on 04/01/14, staff member A11 indicated the cart and medication drawer should be locked because the rooms were not secured, not always staffed, and were accessible to housekeeping staff.</p> <p>8. The facility pharmacy policy "Storage: General", last reviewed 03/2013, indicated, "1.1. Approved drugs and devices shall be stored to ensure their integrity, stability, security, and effectiveness. ...2.2.1. Drugs shall be stored under the proper conditions of sanitation, temperature, light, moisture, ventilation, organization, segregation, safety, and security."</p>		<p>Medical Executive committee and Board of Trustees. The surgery director is responsible for compliance with medication security on carts. The surgery director re-educated anesthesia staff regarding anesthesia cart security of medication and supplies. The OB director educated all nursing staff on infant warmer security of cart and medication. . Measures to prevent reoccurrence. The surgery director will conduct weekly observations for anesthesia cart and infant warmer being locked for 3months consecutive months or until 100% compliance is met. Findings will be presented to Quality Council with reports forwarded to Medical Executive committee and Board of Trustees.</p>		

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S001162	<p>410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8(d)(2)(A)</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:</p> <p>(A) All mechanical equipment (pneumatic, electric, or other) shall be on a documented maintenance schedule of appropriate frequency and with the manufacturer's recommended maintenance schedule.</p> <p>Based on document review and staff interview, the facility failed to comply with manufacturer recommendations for the Hydrocollator located at the South Campus.</p> <p>Findings included:</p> <p>1. The Operation Manual instructions for the use and operation of the Chattanooga Hydrocollator M-2 Master Heating Unit noted the thermostats are extremely sensitive and the slightest adjustment will alter the temperature several degrees. The</p>	S001162	The BioMed Engineer revised the temperature log for the hydrocollator to comply with a range of 160 to 165 degrees. The Rehab Director educated rehab staff on the temperature requirements and documentation Staff reeducation was completed on: April 9, 2014 Measures to prevent reoccurrence. The BioMed Engineer will conduct monthly monitoring of temperature logs for three months or until 100% compliance is met. Findings will be presented to Quality Council with reports forwarded to Medical Executive committee and Board of Trustees.	04/15/2014			

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	<p>recommended operating temperature was 160 to 166 degrees Fahrenheit. The temperature of the water should be checked before using the Steam Packs.</p> <p>2. The South Campus uses a Chattanooga Hydrocollator for the Rehabilitation center. The Hydrocollator Temperature Logs for the Rehabilitation South Campus noted the temperatures of the Hot Pac to be between 150 and 170 degrees Fahrenheit: in contradiction to the manufacturer's requirements. The temperature logs posted at the South Campus revealed 50% of the recorded temperatures to be less than the recommended Hot Pac temperature of 160 degrees Fahrenheit by the manufacturer.</p> <p>3. At 11:30 AM on 4/2/2014, staff member #5 indicated the Chattanooga Hydrocollator Hot Pac temperature range is between 160 and 165 degrees Fahrenheit.</p>			
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	The staff member confirmed the temperature logs have the incorrect Hot Pac temperature range on them.			
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