

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150001		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED 11/02/2011	
NAME OF PROVIDER OR SUPPLIER JOHNSON MEMORIAL HOSPITAL				STREET ADDRESS, CITY, STATE, ZIP CODE 1125 W JEFFERSON ST FRANKLIN, IN 46131			
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S0000	<p>This visit was for a State hospital licensure survey.</p> <p>Dates: 10/31/2011 through 11/2/2011</p> <p>Facility Number: 005001</p> <p>Surveyors: Albert Daeger, CFM, SFPIO Medical Surveyor</p> <p>Saundra Nolfi, RN PH Nurse Surveyor</p> <p>QA: claughlin 11/21/11</p>			S0000			

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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S0330	<p>410 IAC 15-1.4-1 GOVERNING BOARD 410 IAC 15-1.4-1(c)(6)(K)</p> <p>(c) The governing board is responsible for managing the hospital. The governing board shall do the following: (6) Require that the chief executive officer develops policies and programs for the following: (K) Maintaining personnel records for each employee of the hospital which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-ray, as applicable.</p> <p>Based on document review, the facility failed to ensure all employees had their required immunization of Varicella and Rubeola for 26 of 38 hospital employees (P1, P4, P6, P7, P8, P9, P10, P11, P12, P13, P14, P15, P16, P17, P18, P20, P21, P22, P29, P32, P33, P34, P35, P36, P37 and P38)</p> <p>Findings included:</p> <p>1. Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory</p>	S0330	Plan of Correction (Finding 1-4): Other recommendations by ACIP and HICPAC immunization administration for healthcare workers include Hepatitis B, Influenza, and Tetanus, diphtheria, pertussis (Tdap), all strongly recommended. (Attachment S330 A summary of Healthcare Personnel Vaccination Reccomendations, ACIP). JMH was unable to find specific Indiana code requiring rubeola and varicella vaccination/immunity status for hospital employees. (410 IAC 15-1.4-1(c)(6)(K) and Attachment S330 B, "CDC summary of Immunization Administration Requirements for Hospital	01/04/2012			

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	<p>Committee (HICPAC) states, " Because of their contact with patients or infective material from patients, many health-care workers (HCWs)(e.g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative staff) are at risk for exposure to and possible transmission of vaccine-preventable diseases. Maintenance of immunity is therefore an essential part of prevention and infection control programs for HCWs. Optimal use of immunizing agents safeguards the health of workers and protects patients from becoming infected through exposure to infected workers.</p> <p>2. Johnson Memorial Hospital Infection Control Policy, Post-offer Health Assessment Procedure, #IC.3.EPOHA last reviewed April 2009 identified only a MMR was to be done on Rubella and only confirmation from the employee of chickenpox immunity.</p> <p>3. Review of employee personnel records identified 26 of 38 hospital employees did not have documented evidence of immunity against Varicella (P1, P4, P6, P7, P8, P9, P10, P11, P12, P13, P14, P15, P16, P17, P18, P20, P21, P22, P29, P32, P33, P34, P35, P36, P37 and P38).</p>		<p>Employees"). Prevention Plan: Realizing the trending of other State's legislation specifically requiring some of the above ACIP/HICPAC recommendations, (i.e. current Indiana efforts to mandate influenza vaccination), JMH will begin to require serologic immunity testing/or physician documentation for rubeola and varicella beginning with new hires in January 2012. Policy IC.4.EITST Immunizations and Annual Tuberculosis Testing and IC.3.EPOHA Employee Post Offer Health Assessment have been revised to incorporate these new requirements, including actions for any potential outbreak situations (Attachment S330 C and Attachment S330 D). Responsible Person: T. Biasi, Infection Control/Employee Health Professional</p>		

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	4. Review of employee personnel records identified 22 of 38 hospital employees did not have documented evidence of immunity against Rubeola (P4, P6, P7, P8, P9, P10,P13, P14, P15, P16, P17, P18, P20, P22, P29, P32, P33, P34, P35, P36, P37 and P38).			

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S0406	<p>410 IAC 15-1.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-1.4-2(a)(1)</p> <p>(a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. 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.</p> <p>Based on document review, observation and staff interview, the facility failed to ensure Pharmacy Departmental Quality Controls were being monitored as defined by the Pharmacy Departmental Performance Improvement Plan.</p> <p>Findings included:</p> <p>1. Pharmacy Departmental Performance Improvement Plan - 2011 states, "Purpose - The purpose of this departmental PI Plan is to delineate the manner in which we work both within our department and with other departments to accomplish performance improvement. Departmental Quality Controls/Monitors - All drug storage areas are inspected monthly. Departmental Performance Indicators - Accuracy of narcotic administration</p>	S0406	<p>Plan of Correction (Findings 1,2,3): Monitoring logs of refrigerators are checked electronically. Electronic logs (See Attachment S406 A, electronic log date which was reviewed by surveyor) automatically print twice daily in the Pharmacy Department (0600/1800) for review by the Pharmacy Technicians. Temperature logs indicate the date/time of refrigerators who fall outside of the programmed parameters, and time stamped every one (1) hour until the unit is detected in range, documenting the time stamp when this occurs. All medication refrigerators connected to the Pharmacy are included on each report. Auto-print reports serve as the log for the aforementioned refrigerators. Several medication refrigerators within the facility are</p>	01/04/2012			

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	<p>documentation/Pyxis Discrepancy Resolution."</p> <p>2. During the tour of the obstetrical department at 12:35 PM on 10/31/11, accompanied by staff members #1 and #15, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy department, but no monitoring log.</p> <p>3. During the tour of the Coronary Care Unit at 2:25 PM on 10/31/11, accompanied by staff members #1 and #18, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy department, but no monitoring log.</p> <p>4. During the tour of the Medical/Surgical Unit at 3:15 PM on 10/31/11, accompanied by staff members #1 and #18, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy department, but no monitoring log. The bottom of the refrigerator was coated with a dried pinkish material.</p> <p>5. The facility policy regarding refrigerator/freezer temperatures indicated under Medication Refrigerators and Freezers, "1. Refrigerator/freezer temperatures are checked and recorded</p>		<p>not connected electronically to the Pharmacy (i.e. Emergency Department); those refrigerators are monitored twice daily with paper logs in the department. Prevention Plan: CareFusion technicians calibrated the temperature probes on all Pharmacy-connected refrigerators on 11/13/11 and 11/15/11 using Calibration Process (See Attachment S406B Service Confirmation Report and Attachment S406C CareFusion Pyxis SMART Remote Manager Calibration Process). PM was ordered on all medication refrigerators; completed by JMH BioMed department on 1/4/12 Attachment S406 D). JMH plans to continue to monitor electronic logs on those affected refrigerators and use paper logs for refrigeration units not connected electronically to the Pharmacy. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 4): See response for Findings 1,2,3 above. The refrigerator on Med Surg was cleaned of debris on 10/31/11 by the Director of Pharmacy. Prevention Plan: Pharmacy Technicians will continue to monitor for spills during medication checks/routine rounding on refrigerators. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 5, 6, 7): Policy IC.4.FRIG has been reviewed for</p>		

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	<p>twice daily by assigned unit personnel. 2. Refrigerators will be maintained at temperature no less than 35 degrees Fahrenheit and no greater than 41 degrees Fahrenheit."</p> <p>6. The document continued with a list of tasks to be performed if the temperature was out of range, including, "1. Adjust temperature dial. 2. Recheck and record temperature in 30 minutes. ...6. If temperature still outside of range for a medication refrigerator, adjust dial and, if a medication refrigerator or freezer, notify Pharmacy. 7. Recheck and record temperature in no more than 3 hours. 8. If temperature still out of range, contact maintenance and remove device from service per their recommendations. Notify Pharmacy so that medications can be moved to an area of proper temperature. All of the above actions are to be recorded on the temperature log."</p> <p>7. The Pharmacy temperature monitoring log for 10/23/11, indicated the medication refrigerator on CCU ranged between 40 and 52 degrees Fahrenheit (F) for the 24 hour time period. Other refrigerators and ranges for that time period were: T2W (38- 45 F), T3E (35- 45 F), and T3W (36- 43 F). The log lacked any documentation of corrective action. The logs continued to indicate these refrigerators were out of</p>		<p>appropriate temperature ranges, and updated to reflect industry standard temperatures for safe medication refrigeration storage ranging 36-46 degrees Farenheit (Attachment S406E). Refrigerator logs, printed electronically in the Pharmacy twice daily are reviewed by Pharmacy Technicians. Medication refrigerators are small units, and opening the door to remove medication can lower the temperature to below range. TPN is stored in these refrigerators and begins its storage at room temperature immediatly following admixture. Short-term fluctuations in temperature can be expected, based on these variables. Electronic temperature logs indicate the out-of-range timeframe for the CCU refrigerator on 10/23/11 (See Attachment S406 A) was out-of-range four times, returning to appropriate temperature each time slightly more than one hour after initial out of range temperature was recorded, and within safe parameters of medication storage without intervention of staff. Prevention Plan: Continue to monitor electronic records for delays in return to temperature, follow Policy IC.4.FRIG. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 8): Staff member #1 was mistaken regarding alarm notification of nursing staff.</p>		

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	<p>range for 10/23/11- 10/25/11.</p> <p>8. At 12:45 PM on 10/31/11, staff member #1 indicated the refrigerator temperatures were monitored by the Pharmacy Department, but an alarm would also go off in the medication room, alerting nurses if there was a problem.</p> <p>9. At 3:25 PM on 10/31/11, staff member #21 indicated the Pharmacy Department was only staffed from 7:00 AM until 9:00 PM on week-days and from 8:00 AM until 6:00 PM on week-ends. He/she indicated the temperature logs were reviewed each day and adjustments made as needed. He/she indicated there was no alarm in the medication rooms to alert the nurses if there was a problem with the refrigerators. He/she indicated all of the medication refrigerators were set up the same way. The staff member indicated the temperature range of the medication refrigerators should temp between 35 and 41 degrees F.</p> <p>10. At 2:45 PM on 11/02/11, staff member #21 confirmed the long intervals of out-of-range temperatures for the refrigerators and the possibility of efficacy problems with medications stored at out-of range temperatures. The staff member confirmed the Pyxis temperature logs revealed medication refrigerators</p>		<p>Refrigerator logs were interpreted with the thought that temperatures should not drop below/above parameters. Opening the door to a small refrigerator will often raise the temperature to out-of-range limits, the actual time frame for out-of-range temperatures was within 90 minutes on each occasion, each refrigerator (See Attachment S406 F, electronic logs for the dates reviewed by surveyors). Policy IC.4.FRIG (Attachment S406 E) instructs that Pharmacy be notified if, following interventions, the temperature remains out-of-range for more than three (3) hours. This policy has been revised to reflect safe medication storage temperature ranges of 36-46 degrees Fahrenheit. Electronic parameters have been adjusted on all refrigerators to reflect these changes (Attachment S406 G, Device Temperature Configuration). Prevention Plan: Continue to monitor current processes. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 9): Electronic monitoring logs automatically print twice daily in the Pharmacy Pyxis Workstation; the main screen changes color when temperature ranges have been exceeded. Pharmacy Technicians investigate and document interventions for temperatures outside of range not returning to</p>		

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	were out of range for more than 33 hours. He/she also confirmed the lack of any documentation regarding any corrective action taken. The staff member confirmed the medication refrigerators were not a concern on temperature abuse as a quality control indicator.		parameters within policy time limits. Paper logs checked twice daily are thought to be less accurate and more problem-prone than electronic monitoring which indicates precise times of any lapses in appropriate temperature. Prevention Plan: Continue to monitor current processes. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 10): Attachment S406 F are the electronic logs indicated. Several incidents of refrigerator temperatures were recorded out-of-range. Each incience returned to compliant temperatures in less than 90 minutes without intervention of staff. Small refrigerators will commonly drop temperatures somewhat when opened. Plan of Correction: Continue electronic monitoring. IC.4.FRIG (Attachment S406 E) was revised to industry standard safe medication storage ranges of 36-46 degrees Farenheit. Electronic parameters have been changed to reflect these parameters (Attachment S406 G). Responsible Person: L. Harrison, Director, Pharmacy	

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S0554	<p>410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(a)</p> <p>(a) The hospital shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p> <p>Based on observation, document review, and interview, the facility failed to follow manufacturer's directions for dating supplies and discarding to prevent outdated usage in 3 nursing units (med/surg, surgery, and emergency department), failed to store supplies to prevent contamination in the cath lab, and failed to ensure a disinfecting product was used according to manufacturer's directions in the emergency department.</p> <p>Findings included:</p> <ol style="list-style-type: none"> During the tour of the Med/Surg Unit at 3:15 PM on 10/31/11, accompanied by staff members #1 and #18, two glucometer kits were observed with open, but not dated, containers of strips and control solutions. Manufacturer's directions were to date the containers when opened and discard the strips in 4 months and the control solution in 90 days. During the tour of the Cath Lab at 2:35 	S0554	<p>Plan of Correction (Finding 1): Improperly unlabeled glucometer kit materials were discarded on 10/31/11 by the Director of Inpatient Services. Prevention Plan: Signage was placed in the interior as well as the exterior of the glucometer carrying case to remind staff that strips and reagents are dated/discarded appropriately; Department Director has checked to assure proper labeling/disposal of strips and reagents. Responsible Person: S. Pittman Director Inpatient Services</p> <p>Plan of Correction (Finding 2): ProQuaternary was removed from inappropriate storage area on 11/01/11 by the Safety Officer. Prevention Plan: Environmental Services Supervisor has added surveillance and reporting of inappropriate supply/quantity of cleaning chemicals/supplies to the duties of the Environmental Services staff. The Environmental Services Supervisor will follow-up with any issues identified by staff. Responsible Person: M. Pryor, Environmental Services Manager</p> <p>Plan of Correction (Finding #3): The Mounting</p>	01/04/2012	

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	<p>PM on 11/01/11, accompanied by staff members #1, #28, and #29, two gallon containers of Pro-Quaternary All Purpose Disinfectant were observed stored on a metal rack next to boxes of clean gloves and above boxes of sterile needles.</p> <p>3. During the tour of the Pathology/Specimen room in the surgical department at 3:10 PM on 11/01/11, accompanied by staff members #1, #28, and #29, a pint bottle, two-thirds full, of Mounting Medium was observed with a manufacturer's expiration date of 03/2011. A container of Clorox Germicidal wipes with a manufacturer's expiration date of 22 July 11 was also observed on the counter. Staff member #28 indicated the room and supplies were the responsibility of the laboratory.</p> <p>4. During the tour of the emergency department at 3:35 PM on 11/01/11, accompanied by staff members #1 and #30, a glucometer kit was observed with an open, but not dated, container of strips. The 2 bottles of control solution were dated 07/13/11 and the manufacturer's directions were to discard 90 days after opening.</p> <p>5. A spray bottle of ProQuaternary was observed in the soiled room of the department. Staff member #30 indicated</p>		<p>Medium and Clorox wipes were disposed of on 11/01/11 by the Laboratory Supervisor. Prevention Plan: Assessment for outdated/decontamination has been added to the Histology Assistant duties as part of daily checks; checklist reviewed by Supervisor. (See Attachment S554 A, Cyostat and Stain Maintenance and Temperature Log) Responsible Person: J. Alexander, Laboratory Supervisor Plan of Correction (Finding 4): Improperly unlabeled glucometer kits were discarded on 10/31/11 by the Emergency Department Charge Nurse. Prevention Plan: Laboratory personnel will be conducting Quality Monitor checks on glucometers on a monthly basis. Unlabeled/outdated supplies will be reported to the Department Director. Responsible Person: J. Alexander, Laboratory Supervisor, C. Taylor Director Emergency Services Plan of Correction (Finding 5): Education/reminder email was sent to Emergency Department staff and physicians regarding the 10-minute dwell time for disinfection of equipment/beds on 12/29/11. Prevention Plan: Laminated labeling was created for spray bottles used by personnel for disinfection indicating the 10-minute requirement (Attachment S554 B Template for laminate labels). Responsible Person: C. Taylor,</p>				

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	staff used the disinfectant to clean the beds/stretchers between patients. He/she indicated the product was sprayed on and wiped off in less than 5 minutes. The manufacturer's label on the disinfectant indicated the product was to remain on surfaces for 10 minutes before wiping.		Director Emergency Services		

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S0812	<p>410 IAC 15-1.5-5 MEDICAL STAFF 410 IAC 15-1.5-5 (a)(4)(A)(B)(C)(D)(E)(F)(G)(H)(I)(J)(K)</p> <p>(a) The hospital shall have an organized medical staff that operates under bylaws approved by the governing board and is responsible to the governing board for the quality of medical care provided to patients. The medical staff shall be composed of two (2) or more physicians and other practitioners as appointed by the governing board and do the following:</p> <p>(4) Maintain a file for each member of the medical staff that includes, but is not limited to, the following:</p> <p>(A) A completed, signed application. (B) The date and year of completion all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable. (C) A copy of the member's current Indiana license showing the date of licensure and current number or an available certified list provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the medical licensing board. (D) A copy of the member's current Indiana controlled substance registration showing the number, as applicable. (E) A copy of the member's current Drug Enforcement Agency registration showing the number, as applicable (F) Documentation of experience in the practice of medicine.</p>						

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	<p>(G) Documentation of specialty board certification, as applicable. (H) Category of medical staff appointment and delineation of privileges approved. (I) A signed statement to abide by the rules of the hospital. (J) Documentation of current health status as established by hospital and medical staff policy and procedure and federal and state requirements. (K) Other items specified by the hospital and medical staff.</p> <p>Based on documentation review and staff interview, the facility failed to maintain a copy of current Indiana controlled substance registration (CSR) and Drug Enforcement Agency registration (DEA) for 2 of 2 Certified Registered Nurse Anesthetists (CRNA).</p> <p>Findings included:</p> <ol style="list-style-type: none"> Indiana Professional Licensing Agency requires all practitioners to hold one CSR in order to prescribe controlled substances in the State of Indiana. Legally the DEA number is solely to be used for tracking controlled substances. The DEA number, however, is often used by the industry as a general "prescriber" number that is a unique identifier for anyone who can prescribe medication. On 11/1/2011, review of staff members #28 and #29 credentialing file indicated neither staff member had 	S0812	Plan of Correction (Finding 1-5): Surgery Department policy 7801.A.01 Administration of Anesthesia (Attachment S812 AAreV) has been revised to outline the deliniation of services provided by CRNAs. They will be providing services which include administration of medications only during the operative period. This poicy was approved by the Chief Nursing Officer on 4/9/12, it will be submitted to the Surgery Section for approval at the May 2012 meeting. Complications requiring medications will be addressed with the development of protocols (written order sets) to be authenticated by a member of the Medical Staff (anesthesiologist or surgeon). Protocol is reviewed and approved by the Medical Staff annually. The job description of the CRNA has been amended to reflect focus on the operative period. Communication of the changes to policy were re-sent 4/9/12 by the	04/11/2012			

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	<p>documented proof of a CSR and/or DEA registration on file.</p> <p>3. Medical Staff by-laws last approved 1/25/2011 Article V section 5.1-2 states, "The applicant must sign the application, and in doing so; Provides information regarding previously successful or current pending challenges to any licensure or registration (state or district or Drug Enforcement Administration)."</p> <p>4. At 9:00 AM on 11/1/2011, staff member #23 indicated he/she was unable to locate either the CSR or DEA for staff members #28 and #29.</p> <p>5. At 10:45 AM on 11/2/2011, staff member #4 indicated CRNA staff members #23 and #24 ordered controlled substances as evidenced on medical records.</p> <p>6. Staff member #4 provided the most recent outpatient surgery cases that CRNA #23 and #24 assisted in. CRNA staff member #23 Post Anesthesia orders for 3 separate surgeries dated 10/19/11, 10/18/11 and 10/23/11 were provided. The CRNA signed the the order. The controlled substances included in these orders were Fentanyl, Demerol and Morphine. CRNA staff member #24 Post Anesthesia orders for 3 separate surgeries</p>		Chief Nursing Officer to the CRNAs, the Medical Director of Anesthesia, and the Chief Medical Officer. Responsible Person: A. Trackwell, CNO				

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	dated 10/19/2011, 10/18/11, and 10/19/2011 were provided. The CRNA signed the orders. The controlled substances included in these orders were Fentanyl and Morphine.				

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S0936	<p>410 IAC 15-1.5-6 NURSING SERVICE 410 IAC 15-1.5-6 (b)(6)</p> <p>(b) The nursing service shall have the following:</p> <p>(6) All nursing personnel shall demonstrate and document competency in fulfilling assigned responsibilities.</p> <p>Based on document review and staff interview, the facility failed to ensure agency Registered Nurses are competent in IV Medication Administration (P1, P2, and P3).</p> <p>Findings included:</p> <p>1. Competency Policy 7.1.1 last reviewed 1/13/2010 states, "Purpose - To verify and provide documentation of all hospital staffs' knowledge, skills, and abilities to fulfill their assigned duties and responsibilities as defined by their job description. Scope - All hospital employees and contracted staff. Policy Statement - The competency of each staff member to perform procedures and operate equipment will be documented throughout his/her association with the hospital. Procedure - Department Directors are responsible for coordinating, assessing and documenting the orientation process. Completing re-in-servicing/training, when necessary, while monitored by a qualified</p>	S0936	<p>Plan of Correction (Finding 1,2,3): Agency personnel mentioned in the citation had completed department orientation and checklist including review of relevant policy; an additional materials have been added to orientation to including proficiency/return demonstration of use of the make and model of JMH pumps (Attachment S936 A). Bedside Medication Verification training will take place via an online module (see Attachment S936 B, BMV Questions for the module post-test). Prevention Plan: Agency personnel will complete additional requirements as above upon department orientation. Responsible Person: A. Trackwell, CNO</p>	01/04/2012	

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	<p>employee."</p> <p>2. The hospital could not provide any documentation of inservice training on IV Medication Administration on agency staff members P1, P2, and P3 conducted by hospital employees as defined in hospital policy.</p> <p>3. A 2:45 PM on 11/2/2011, staff member #4 indicated all registered nurses except those located in physician offices are to receive annual training on IV Medication Administration and Blood Administration. However, all three agency staff members are assigned to Medical/Surgical but are not allowed to administer blood but need to be trained in IV Medication administration. The staff member indicated hospital employees have not confirmed compliancy in IV Medication Administration on the three agency staff members.</p>						

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S1022	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(B)</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>(B) Appropriate storage conditions.</p> <p>Based on observation, document review, and interview, the facility failed to ensure all medications were stored at the required temperatures and medication refrigerators were clean and sanitary.</p> <p>Findings included:</p> <ol style="list-style-type: none"> During the tour of the obstetrical department at 12:35 PM on 10/31/11, accompanied by staff members #1 and #15, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy department, but no monitoring log. During the tour of the Coronary Care Unit at 2:25 PM on 10/31/11, accompanied by staff members #1 and #18, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy 	S1022	<p>Plan of Correction (Findings 1,2): Monitoring logs of refrigerators are checked electronically. Electronic logs (See Attachment S406 A, electronic log date which was reviewed by surveyor) automatically print twice daily in the Pharmacy Department (0600/1800) for review by the Pharmacy Technicians. Temperature logs indicate the date/time of refrigerators who fall outside of the programmed parameters, and time stamped every one (1) hour until the unit is detected in range, documenting the time stamp when this occurs. All medication refrigerators connected to the Pharmacy are included on each report. Auto-print reports serve as the log for the aforementioned refrigerators. Several medication refrigerators within the facility are not connected electronically to the Pharmacy (i.e. Emergency Department); those refrigerators</p>	01/04/2012			

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	<p>department, but no monitoring log.</p> <p>3. During the tour of the Medical/Surgical Unit at 3:15 PM on 10/31/11, accompanied by staff members #1 and #18, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy department, but no monitoring log. The bottom of the refrigerator was coated with a dried pinkish material.</p> <p>4. The facility policy regarding refrigerator/freezer temperatures indicated under Medication Refrigerators and Freezers, "1. Refrigerator/freezer temperatures are checked and recorded twice daily by assigned unit personnel. 2. Refrigerators will be maintained at temperature no less than 35 degrees Fahrenheit and no greater than 41 degrees Fahrenheit."</p> <p>The document continued with a list of tasks to be performed if the temperature was out of range, including, "1. Adjust temperature dial. 2. Recheck and record temperature in 30 minutes. ...6. If temperature still outside of range for a medication refrigerator, adjust dial and, if a medication refrigerator or freezer, notify Pharmacy. 7. Recheck and record temperature in no more than 3 hours. 8. If temperature still out of range, contact</p>		<p>are monitored twice daily with paper logs in the department. Prevention Plan: CareFusion technicians calibrated the temperature probes on all Pharmacy-connected refrigerators on 11/13/11 and 11/15/11 using Calibration Process (See Attachment S406B Service Confirmation Report and Attachment S406C CareFusion Pyxis SMART Remote Manager Calibration Process). PM was ordered on all medication refrigerators; completed by JMH BioMed department on 1/4/12 Attachment S406 D). JMH plans to continue to monitor electronic logs on those affected refrigerators and use paper logs for refrigeration units not connected electronically to the Pharmacy. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 3): See above comments for Findings 1,2; The refrigerator on Med Surg was cleaned of debris on 10/31/11 by the Director of Pharmacy. Prevention Plan: Pharmacy Technicians will continue to monitor for spills during medication checks/routine rounding on refrigerators. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 4,5): Policy IC.4.FRIG has been reviewed for appropriate temperature ranges, and updated to reflect industry standard temperatures for safe</p>		

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	<p>maintenance and remove device from service per their recommendations. Notify Pharmacy so that medications can be moved to an area of proper temperature. All of the above actions are to be recorded on the temperature log."</p> <p>5. The Pharmacy temperature monitoring log for 10/23/11, indicated the medication refrigerator on CCU ranged between 40 and 52 degrees Fahrenheit (F) for the 24 hour time period. Other refrigerators and ranges for that time period were: T2W (38- 45 F), T3E (35- 45 F), and T3W (36- 43 F). The log lacked any documentation of corrective action. The logs continued to indicate these refrigerators were out of range for 10/23/11- 10/25/11.</p> <p>6. At 12:45 PM on 10/31/11, staff member #1 indicated the refrigerator temperatures were monitored by the Pharmacy Department, but an alarm would also go off in the medication room, alerting nurses if there was a problem.</p> <p>7. At 3:25 PM on 10/31/11, the Pharmacy Director, staff member #21, indicated the Pharmacy Department was only staffed from 7:00 AM until 9:00 PM on week-days and from 8:00 AM until 6:00 PM on week-ends. He/she indicated the temperature logs were reviewed each day and adjustments made as needed.</p>		<p>medication refrigeration storage ranging 36-46 degrees Fahrenheit (Attachment S406E). Refrigerator logs, printed electronically in the Pharmacy twice daily are reviewed by Pharmacy Technicians. Medication refrigerators are small units, and opening the door to remove medication can lower the temperature to below range. TPN is stored in these refrigerators and begins its storage at room temperature immediately following admixture. Short-term fluctuations in temperature can be expected, based on these variables. Electronic temperature logs indicate the out-of-range timeframe for the CCU refrigerator on 10/23/11 (See Attachment S406 A) was out-of-range four times, returning to appropriate temperature each time slightly more than one hour after initial out of range temperature was recorded, and within safe parameters of medication storage without intervention of staff. Prevention Plan: Continue to monitor electronic records for delays in return to temperature, follow Policy IC.4.FRIG. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 6, 7): Staff member #1 was mistaken regarding alarm notification of nursing staff. Refrigerator logs were interpreted with the thought that temperatures should not drop</p>		

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	<p>He/she indicated there was no alarm in the medication rooms to alert the nurses if there was a problem with the refrigerators. He/she indicated all of the medication refrigerators were set up the same way.</p> <p>8. At 2:45 PM on 11/02/11, staff member #21 confirmed the long intervals of out-of-range temperatures for the refrigerators and the possibility of efficacy problems with medications stored at out-of range temperatures. He/she also confirmed the lack of any documentation regarding any corrective action taken.</p>		<p>below/above parameters. Opening the door to a small refrigerator will often raise the temperature to out-of-range limits, the actual time frame for out-of-range temperatures was within 90 minutes on each occasion, each refrigerator (See Attachment S406 F, electronic logs for the dates reviewed by surveyors). Policy IC.4.FRIG (Attachment S406 E) instructs that Pharmacy be notified if, following interventions, the temperature remains out-of-range for more than three (3) hours. This policy has been revised to reflect safe medication storage temperature ranges of 36-46 degrees Fahrenheit. Electronic parameters have been adjusted on all refrigerators to reflect these changes (Attachment S406 G, Device Temperature Configuration). Prevention Plan: Continue to monitor current processes. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 8): Electronic monitoring logs automatically print twice daily in the Pharmacy Pyxis Workstation; the main screen changes color when temperature ranges have been exceeded. Pharmacy Technicians investigate and document interventions for temperatures outside of range not returning to parameters within policy time limits. Paper logs checked twice daily are thought to be less</p>		

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			accurate and more problem-prone than electronic monitoring which indicates precise times of any lapses in appropriate temperature. Prevention Plan: Continue to monitor current processes. Responsible Person: L. Harrison, Director Pharmacy		

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S1026	<p>410 IAC 15-1.5-7 PHARMACEUTICAL SERVICES 410 IAC 15-1.5-7 (d)(2)(D)</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>(D) Documentation and accountability for an accurate accounting of controlled substances from the time of receipt in the institution through the administration to the patient or subsequent removal from general stock and reporting of all abuses and losses of controlled substances.</p> <p>Based on observation, medical record review, and interview, the facility failed to ensure a controlled substance was stored and disposed of according to standards of practice.</p> <p>Findings included:</p> <p>1. During the tour of the surgical department at 2:35 PM on 11/01/11, accompanied by staff members #1 and #29, a syringe of medication was observed taped inside a cabinet door in the nurses' station of the pre-op area. The syringe had the manufacturer's labeling of Morphine Sulphate 10 milligrams per milliliter and contained 0.4 milliliter of</p>	S1026	Plan of Correction (Finding 1,2,3): Medication was appropriately wasted and documented as such upon discovery on 11/01/11 by the Director of Surgical Services and a staff nurse. Prevention Plan: Issue of inappropriate handling, documentation, and accountability for controlled substances was addressed with the Surgery Department staff present on 11/01/11 by the Director of Surgical Services, and at house-wide Charge Nurse meeting on 11/03/11 by the Chief Nursing Officer. Rounding in the Surgical Services area by the Chief Nursing Officer has revealed no further deviation from responsible handling/disposal of medications. Responsible	11/03/2011			

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	<p>solution. A patient identification sticker was wrapped around the syringe.</p> <p>2. Upon review of the patient's record, documentation indicated 6 milligrams of the medication were given earlier in the day. The patient was no longer at the facility.</p> <p>3. At 2:45 PM on 11/01/11, staff members #28 and 29 indicated the nurse probably kept the medication in case the patient required more, then failed to waste it with another staff member. Staff confirmed this was not according to hospital policy.</p>		Person: A. Trackwell, CNO		

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S1118	<p>410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8 (b)(2)</p> <p>(b) The condition of the physical plant and the overall hospital environment shall 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 shall be created or maintained which may result in a hazard to patients, public, or employees.</p> <p>Based on observation, document review and interview, the facility failed to ensure the environment was maintained in a safe and healthy manner for patients, visitors and guests in the Maintenance Department, Equipment Storage Room, Radiology Department, Obstetrical Department and in the Emergency Department.</p> <p>Findings Included:</p> <p>1. Johnson Memorial Hospital Safety Management Plan last reviewed November 2010 states, "Johnson Memorial Hospital is designed in accordance with the mission, services offered, and needs of the customers served, as well as conforming to applicable laws and regulations including but not limited to OSHA. The safety</p>	S1118	<p>Plan of Correction (Finding 1,2,3,6,7): Appropriate PPE was placed in the storage room in Radiology Ultrasound rooms on 10/31/11 by the Director of Medical Imaging. Staff was instructed on proper use of PPE to prevent injury both verbally at the time of the incident. Email confirmation of practice change was sent to the Department Director from the ultrasound supervisor (Attachment S1118 A). Prevention Plan: Inspection of PPE/appropriate usage part of Infection Control Rounds, performed by Infection Control Professional (Attachment S1118 B). Responsible Person: R. Collins, Director Medical Imaging, T. Biasi, Infection Control Professional</p> <p>Plan of Correction (Finding 4,5,8): A new bench grinder was purchased for the department with the appropriate safety guards/work rests. (Attachment S1118 C Purchase</p>	01/04/2012			

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	<p>program utilizes criteria within 'Life Safety Code 101' and the ..."</p> <p>2. CIDEX OPA solution manufacturer's Warning label states, "Avoid contact with eyes, skin or clothing. Wear eye protection, fluid-resistant gowns or aprons and gloves when handling or pouring."</p> <p>3. Occupational Health and Safety Services (OSHA) general standard at 1910.151 applies when necessary, facilities for drenching or flushing the eyes 'shall be provided within the work area for immediate emergency use. In applying these general terms, OSHA would consider the guidelines set by such sources as American National Standards Institute (ANSI) Z358.1 -1998, Emergency Eyewash and Shower Equipment, which states, at section 7.4.4, that eyewash facilities are to be located to require no more than 10 seconds to reach but that where a strong acid or caustic is used, the unit should be immediately adjacent to the hazard."</p> <p>4. OSHA 29 CFRb1915.134 requires Floor stand and bench mounted abrasive wheels used for external grinding shall be provided with safety guards (protection hoods).</p> <p>5. OSHA 29 CFR 1910.215 requires</p>		<p>Order 087751). Prevention Plan: PM on new equipment to assure it does not fall into disrepair. Responsible Person: C. Snyder, Facilities ManagerPlan of Correction (Finding 9): A Work Order was placed for eyewash station in the Environmental Services equipment storage room on 11/3/11; this task was completed on 11/4/11. (Attachment S1118 D Work Order 24042). Prevention Plan: Assure eyewash stations in appropriate locations throughout the facility. Responsible Person: C. Snyder, Facilities ManagerPlan of Correction (Finding 10, 11, 12, 15): Instrument cleaning area has been centralized for the Maternity/Nursing into a single soiled utility room. A PPE station was created, and detailed instructions regarding the appropriate cleaning of instruments was posted on the wall (Attachment S1118 E photos of Maternity Department wall). Prevention Plan: Observance of PPE use monitored by Infection Control on rounds (Attachment S1118 B Infection Control Rounds checklist). Responsible Person: T. Biasi, Infection Control Professional, M. Bisesi, Director Maternity ServicesPlan of Correction (Finding 13, 14, 16): PPE was added to the soiled utility room in the Emergency Department on 11/01/11. An eyewash station has been ordered for the area (Attachment</p>				

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	<p>work-rests shall be used to support the work for bench grinders. They shall be of rigid construction and designed to be adjustable to compensate for wheel wear.</p> <p>6. At 2:20 PM on 10/31/2011, Radiology Department was toured. CIDEX OPA disinfecting stations were mounted in the two Ultrasound rooms. Neither room had any personal protective equipment (PPE) stored in the room.</p> <p>7. At 2:25 PM on 10/31/2011, staff member #7 explained how he/she prepares the high level disinfectant for disinfecting the vaginal probes. The staff member indicated he/she does not use an apron and eye protection when disinfecting the probes.</p> <p>8. At 2:30 PM on 10/31/2011, the Maintenance Shop was toured. The room had a bench grinder within the room. The bench grinder was observed with the 2 abrasive wheels with heavy accumulation and wear on the both wheel surfaces. The bench mounted grinder was observed without any safety guards and work rests. The safety equipment was removed by staff member prior to the inspection and could not be located by staff member #11.</p> <p>9. At 2:45 PM on 10/31/2011, the Equipment Storage Room was observed</p>		S1118 F PO 088591, 087757, 087752). Plan of Correction: A facility-wide survey was done by Plant Operations and the Safety Coordinator to determine if other areas could benefit from eyewash stations; units have been ordered for those areas (Attachment S1118 F). Responsible Person: C. Snyder, Facilities Manager.				

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	<p>with two floor scrubbers that were being charged by two battery chargers and the battery chargers were on a shelf located behind two floor scrubbers. One of the two scrubbers were inspected and discovered 4 acid batteries within it. Two batteries were observed with turquoise color sulfuric acid being discharged around two terminals. The room did not have an eyewash station to flush eyes with water in case of sulfuric acid splash into a staff member's eyes.</p> <p>10. During the tour of the soiled room on the obstetrical area at 12:35 PM on 10/31/11, accompanied by staff members #1 and #15, a sink used for cleaning soiled vaginal instruments was observed without an eyewashing device. Gloves and eye protection were observed in the room, but not gowns or aprons. The enzymatic cleaner, Endozime, and the disinfectant cleaner, Pro Quaternary, were observed near the sink.</p> <p>11. The labels on both products indicated goggles or face shields, rubber gloves, and aprons should be worn when handling the products and if splashed, eyes should be flushed for 15- 20 minutes.</p> <p>12. During the tour of the nursery at 12:50 PM on 10/31/11, accompanied by staff members #1 and #15, the sink used</p>						

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	<p>to clean the circumcision instruments was observed without an eyewashing device. A container of Endozime was observed near the sink for use. Only gloves were observed in this area.</p> <p>13. During the tour of the Emergency Department at 3:55 PM on 11/01/11, accompanied by staff members #1 and #30, a pump bottle of Pro Quaternary disinfectant used to mix the solution for the small spray bottles was observed in the soiled room. The room lacked an eyewashing device and any personal protective equipment other than gloves.</p> <p>14. The facility's Safety Management Plan, dated November 2010, stated under Procedure, "[The facility] is designed in accordance with its mission, services offered, and needs of the customers served, as well as conforming to applicable laws and regulations including but not limited to OSHA. The safety program utilizes criteria within 'Life Safety Code 101' and the 'Guidelines for Construction and Equipment of Hospitals and Medical Facilities' to design the environment."</p> <p>15. At 1:55 PM on 10/31/11, staff member #17 indicated he/she double gloved when washing instruments in the soiled room of the obstetrical department.</p>				

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	<p>He/she indicated the Lab, located on another floor, had an eyewash station.</p> <p>16. At 4:00 PM on 11/01/11, staff member #30 in the emergency department, indicated the nearest eyewash station was in the Lab, which was approximately 100 feet away through two coded doors.</p>				

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S1160	<p>410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 15-1.5-8(d)(1)</p> <p>(d) The equipment requirements are as follows:</p> <p>(1) All equipment shall be in good working order and regularly serviced and maintained.</p> <p>Based on observation, document review, and interview, the facility failed to ensure periodical preventive maintenance was performed on the Pyxis Med Station 3500.</p> <p>Findings included:</p> <ol style="list-style-type: none"> During the tour of the obstetrical department at 12:35 PM on 10/31/11, accompanied by staff members #1 and #15, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy department, but no monitoring log. During the tour of the Coronary Care Unit at 2:25 PM on 10/31/11, accompanied by staff members #1 and #18, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy department, but no monitoring log. During the tour of the Medical/Surgical Unit at 3:15 PM on 	S1160	<p>Plan of Correction (Findings 1,2,3): Monitoring logs of refrigerators are checked electronically. Electronic logs (See Attachment S406 A, electronic log date which was reviewed by surveyor) automatically print twice daily in the Pharmacy Department (0600/1800) for review by the Pharmacy Technicians. Temperature logs indicate the date/time of refrigerators who fall outside of the programmed parameters, and time stamped every one (1) hour until the unit is detected in range, documenting the time stamp when this occurs. All medication refrigerators connected to the Pharmacy are included on each report. Auto-print reports serve as the log for the aforementioned refrigerators. Several medication refrigerators within the facility are not connected electronically to the Pharmacy (i.e. Emergency Department); those refrigerators are monitored twice daily with paper logs in the department. The medication refrigerator on Med/Surg was cleaned of debris</p>	01/04/2012	

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	<p>10/31/11, accompanied by staff members #1 and #18, the medication refrigerator was observed with a temperature monitoring device connected to the pharmacy department, but no monitoring log. The bottom of the refrigerator was coated with a dried pinkish material.</p> <p>4. The facility policy regarding refrigerator/freezer temperatures indicated under Medication Refrigerators and Freezers, "1. Refrigerator/freezer temperatures are checked and recorded twice daily by assigned unit personnel. 2. Refrigerators will be maintained at temperature no less than 35 degrees Fahrenheit and no greater than 41 degrees Fahrenheit."</p> <p>5. The document continued with a list of tasks to be performed if the temperature was out of range, including, "1. Adjust temperature dial. 2. Recheck and record temperature in 30 minutes. ...6. If temperature still outside of range for a medication refrigerator, adjust dial and, if a medication refrigerator or freezer, notify Pharmacy. 7. Recheck and record temperature in no more than 3 hours. 8. If temperature still out of range, contact maintenance and remove device from service per their recommendations. Notify Pharmacy so that medications can be moved to an area of proper</p>		<p>by the Director of Pharmacy on 10/31/11. Prevention Plan: CareFusion technicians calibrated the temperature probes on all Pharmacy-connected refrigerators on 11/13/11 and 11/15/11 using Calibration Process (See Attachment S406B Service Confirmation Report and Attachment S406C CareFusion Pyxis SMART Remote Manager Calibration Process). PM was ordered on all medication refrigerators; completed by JMH BioMed department on 1/4/12 Attachment S406 D). JMH plans to continue to monitor electronic logs on those affected refrigerators and use paper logs for refrigeration units not connected electronically to the Pharmacy. Pharmacy technicians will monitor for spills during regular rounds. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 4,5,6): Policy IC.4.FRIG has been reviewed for appropriate temperature ranges, and updated to reflect industry standard temperatures for safe medication refrigeration storage ranging 36-46 degrees Farenheit (Attachment S406E). Refrigerator logs, printed electronically in the Pharmacy twice daily are reviewed by Pharmacy Technicians. Medication refrigerators are small units, and opening the door to remove medication can lower the temperature to below range. TPN</p>				

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	<p>temperature. All of the above actions are to be recorded on the temperature log."</p> <p>6. The Pharmacy temperature monitoring log for 10/23/11, indicated the medication refrigerator on CCU ranged between 40 and 52 degrees Fahrenheit (F) for the 24 hour time period. Other refrigerators and ranges for that time period were: T2W (38- 45 F), T3E (35- 45 F), and T3W (36- 43 F). The log lacked any documentation of corrective action. The logs continued to indicate these refrigerators were out of range for 10/23/11- 10/25/11.</p> <p>7. At 2:00 PM on 11/01.2011, staff member #21 indicated the Pyxis Medstation 3500 was purchased about 2 years ago and the system has never had a preventive maintenance conducted on it. The staff member indicated the vendor has arrived several times to the facility to work on the software but has never left any documentation on work that was done. The staff member indicated the temperature gauges on the units have never been calibrated to make sure of proper calibration. The staff member confirmed after reviewing the Pyxis computer temperature log print outs, the documentation revealed 6 out of 13 medication refrigerators were not in the proper temperature range of 35 to 41 degrees F on a consisted basis.</p>		<p>is stored in these refrigerators and begins its storage at room temperature immediately following admixture. Short-term fluctuations in temperature can be expected, based on these variables. Electronic temperature logs indicate the out-of-range timeframe for the CCU refrigerator on 10/23/11 (See Attachment S406 A) was out-of-range four times, returning to appropriate temperature each time slightly more than one hour after initial out of range temperature was recorded, and within safe parameters of medication storage without intervention of staff. Prevention Plan: Continue to monitor electronic records for delays in return to temperature, follow Policy IC.4.FRIG. Responsible Person: L. Harrison, Director PharmacyPlan of Correction (Finding 7,8): PM by CareFusion was completed on 11/13 and 11/15, with temperature probes calibrated (Attachment S406 B Service Confirmation Report). Policy IC.4.FRIG was reviewed and revised for standard medication storage temperatures of 36-46 degrees F (Attachment S406 E), Temperature parameters were re-programmed to match policy update (Attachment 406 G), JMH BioMed department conducted PM on the refrigerators on 1/4/12 (Attachment 406D). Owner's Manual for the Pyxis 3500 has</p>		

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	<p>8. At 2:45 PM on 11/02/11, staff member #21 confirmed the long intervals of out-of-range temperatures for the refrigerators and the possibility of efficacy problems with medications stored at out-of range temperatures. He/she also confirmed the lack of any documentation regarding any corrective action taken.</p> <p>9. At 3:10 PM on 11/2/2011, staff members #11 and #24 confirmed the hospital does not have an owner's manual on the Pyxis Medstation 3500 and after further research on the medication dispensing system, the hospital staff could not determine what a proper preventive maintenance needs to be performed on the system. Staff member #24 indicated the system was never put on a preventive maintenance schedule and after reviewing the temperature logs, the Pyxis Medstation 3500 needs to be looked at by the manufacturer.</p>		<p>been present in the department since the purchase of the equipment; questions regarding the function of the SMART Remote Manager (the temperature probe/reporting system) were not easily answered using the manual. CareFusion has supplied JMH with additional resources (Attachment S1022 A Using the Pyxis SMART Remote Manager for the management of refrigerated and other temperature-sensitive medications). Prevention Plan: Continue regularly scheduled preventive maintenance and policy/process review. Responsible Person: L. Harrison, Pharmacy Director</p>		