

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150076		X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____		X3) DATE SURVEY COMPLETED 09/29/2015	
NAME OF PROVIDER OR SUPPLIER SAINT JOSEPH REGIONAL MEDICAL CENTER - PLYMOUTH				STREET ADDRESS, CITY, STATE, ZIP CODE 1915 LAKE AVE PLYMOUTH, IN 46563			
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S 0000 Bldg. 00	<p>This visit was for a State hospital licensure survey.</p> <p>Dates: 9/28/2015 - 9/29/2015</p> <p>Facility Number: 005070</p> <p>QA: JC 10/20/15</p> <p>IDR Committee met on 12-07-15, no changes made. JL</p>			S 0000			
S 0554 Bldg. 00	<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 document review, observation, and interview, the facility failed to ensure four operating rooms (OR) met the required temperature as defined by</p>			S 0554	<p>November 17, 2015 OR temps OR Environmental Conditions –Operational Guidelines: temperature, relative humidity, pressurization: The Director of OR is responsible for the</p>		11/17/2015

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>hospital policy and American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE) guidelines.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Saint Joseph Regional Medical Center Infection Control Program (last reviewed 2/12/2014) references Association of PeriOperative Registered Nurses (AORN) as it relates to infection control practices. AORN supports the American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE) guidelines on temperature and humidity ranges for perioperative settings. The Operating Rooms temperature range should be between 68 F and 73 F. 2. Saint Joseph Regional Medical Center Humidity Monitoring and Response policy (last approved 9/9/2014) indicated Plant Operations staff will work with Surgery to increase room temperature until it is back in an acceptable range. 3. The operating rooms Surgery Relative Humidity & Room Temperature Log stated, "The recommended room temperature is 68 to 73 degrees Fahrenheit." 		<p>oversight of the managing and monitoring environmental conditions in the ORs for comfort and safety of patients, colleagues, surgeon & anesthesia care partners and others. A priority is placed on maintaining normothermia of the patients undergoing surgery throughout the peri-operative period. The surgical teams collaborate closely with Facility HVAC engineers to maintain comfort, including temperature, relative humidity, and positive pressure during surgical care with emphasis on daily operational aspects in the Surgery Suite and other areas that provide invasive procedures, e.g. Cath. Lab, C-Section Rooms, & Interventional Radiology. The OR Temperature / Humidity Monitoring and Response policy and procedure was reviewed and updated on 11/9/2015 and will go to the EOC/IC meeting for approval on 11/18/2015. We contacted Trinity Health System Office colleagues who shared that they have begun a process to engage key stakeholders, e.g. AORN, ASHRAE, FGI, in a workgroup that has extended invitation to leaders within Centers for Medicare & Medicaid Services (CMS), i.e. Thomas E. Hamilton (CMS/CMCS) Chief of Survey and Certification Guidance (SCG), to reconcile differences between design standards/guidelines and daily</p>		

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	<p>4. Reviewed temperature log for OR #1 indicated temperature was documented as 62.6 to 65.0 degrees Fahrenheit for month of August 2015.</p> <p>5. Reviewed temperature log for OR #2 indicated temperature was documented as 60.7 to 66.7 degrees Fahrenheit for month of August 2015.</p> <p>6. Reviewed temperature log for OR #3 indicated temperature was documented as 61.0 to 64.6 degrees Fahrenheit for month of August 2015.</p> <p>7. Reviewed temperature log for OR #4 indicated temperature was documented as 61.0 to 65.0 degrees Fahrenheit for month of August 2015.</p> <p>8. At 3:00 PM on 9/28/2015, staff member #8 (Facility/Plant Operation) confirmed the recorded temperatures of the operating rooms did not meet the recommended minimum temperatures of 68 degrees Fahrenheit. The staff member indicated the physicians lower the operating room temperatures as low as 60 degrees Fahrenheit.</p>		<p>operational needs of the surgeons and perioperative team performing surgery. System Office colleagues will keep the SJRMC team apprised of progress in deliberations by this ad hoc workgroup A multidisciplinary team at SJRMC has also reviewed ISDH guidance on environmental conditions in the OR as well as conducted a literature review to identify best practices. The team found there is minimal to no risk of infection to patients by having the OR rooms at a temperature below 68 degrees F (specified in lower limit in ASHRAE 170) as long as the patient's temperature is being monitored and maintained in normothermia during the procedure and in recovery. Further both ASHRAE 170 and ISDH guidelines include and recognize the need of the surgical team to alter OR temperature as highlighted below during daily operations of the Surgery Suite. Surgeons and operating room staff gown up to protect the patient as well as themselves. The high activity levels and the PPE require cooler OR room temperatures to accommodate surgeon and staff comfort during procedures. During our recent ISDH survey, the temperature logs from August 2015 at SJRMC-Plymouth were reviewed. We conducted a chart audit of the cases performed in August 2015 that corresponds to</p>		

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			<p>the logs reviewed during survey and found that all cases (104/104) had patient temperatures monitored during the procedure and in recovery. The SCIP patient temperature measure of 96.8 or greater was met. It is standard practice to monitor patient's temperatures and manage the patient's temperature by various methods, warmblankets, warm fluids, warming machines. The frequency of outcomes, inclusive of patient complications, in the month of August 2015 was no different than prior to or after the month of August 2015. A risk assessment was completed as follows: Indiana General Assembly Administrative Code refersto Indiana Administrative Code (IAC) Title 410 – Indiana State Department of Health (ISDH) 2001 Guidelines for Construction and Equipment of Hospital and Medical Facilities, Article 15 – Hospital Licensure Rules, Rule 1.5-8 Physicalplant, maintenance and environmental services number 12:</p> <p>"Some surgeons may require room temperatures that are outside of the indicatedrange. All operating room design conditions shall be developed in consultation with surgeons, anesthesiologists and nursing staff." The temperatures in the document are "DesignParameters". The intention is that the OR rooms</p>	

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			<p>meet these as minimums, not exclusive of a wider range. The Chair of ASHRAE 170(Christopher Rousseau) has confirmed that this is a design standard but the language above does not preclude temperatures outside the design range in 170. [personal communication, 11/9/2015] Surgeons and operating room staff gown up to protect the patient as well as themselves. The high activity levels and the PPE require cooler OR room temperatures to accommodate surgeon and staff comfort during procedures. Physicians usually call for temperatures in the low 60's F. The OR Room HVAC systems have been designed to accommodate the lower temperatures. Patient core temperatures are a major consideration.</p> <ul style="list-style-type: none"> · Warm IV's and fluid irrigation is utilized · Warm blankets are used · Forced air warming devices are used · Temperature is monitored during and post procedures · All are of the above are part of the documentation <p>Peri-operative patient temperatures will be monitored during monthly chart audits conducted by the OR department and reported to the Surgery committee, Team 3/Provision of Care and to the Quality Committee of the Board</p>	

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			<p>for 6 months. Random audits will be conducted thereafter.</p> <p>Response 12/17/2015 0554 What standard are you using to make temperature changes for the comfort of the physician and staff? We are using standards from ASHRAE, 55 and 170. The ASHRAE 55 standard graph is attached. ASHRAE 170, note (o): Surgeons or surgical procedures may require room temperatures and or air distribution methods that exceed the minimum indicated ranges. The level of attire for the surgeons and peri-operative team results in an elevated CLO level and the higher MET level for the activity of this team which calls for a temperature up to 8 degrees lower than the design range per ASHRAE 55. Response - December 30, 2015 0554 Please provide an Infection Control standard you are following and not a design guideline for construction to change the temperatures outside of acceptable standards of practice to accommodate the surgical team. <u>The IC standards that we are following to accommodate both the patient and the surgical team are: HICPAC, CDC. GUIDELINE FOR PREVENTION OF SURGICAL SITE INFECTION, 1999. Infect Control Hosp Epidemiol 1999;20:247-78. CDC Guidelines for Environmental</u></p>	

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			<p><u>Infection Control in Healthcare Facilities, 2003</u> Additionally, the environment of care section of AORN is a recommendation, not required temperature range for the operating rooms. Per the EOC section of AORN, "Each organization can determine an operating room temperature range in conjunction with IC and Facilities". January 19, 2016</p> <p>The following AORN guidance does cite the ASHRAE 170 as a design standard however it permits local risk assessment involving a multiple of disciplines, e.g. perioperative nursing/clinicians, infection preventionist, HVAC engineer, etc. to identify an optimal temperature for the surgical team and strategies to maintain normothermia of the patient. AORN Guidance Regarding temperature in Operating Room:</p> <ul style="list-style-type: none"> · What are the recommended temperature ranges for an operating room? · The recommended temperature range in an operating room is between 68°F and 75°F. Collaborate with infection prevention, and facility engineers when determining temperature ranges. Each facility should determine acceptable ranges for temperature in accordance with regulatory and accrediting agencies. · Resources: Guideline for a safe environment of care, part 2. In: Guidelines for Perioperative 	

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			<p>Practice. Denver, CO: AORN, Inc. <i>Updated March 3, 2015.</i> We have been in consultative contact with AORN regarding their position on the temperature range in the ORs. Their position is only a recommendation as it is up to each facility to determine the temperature range in the ORs. They referred us to the following:</p> <ol style="list-style-type: none"> 1. The Expert Interim statement, <i>Joint Interim Guidance, HVAC in the Operating Room and Sterile Processing Department, September 21, 2015.</i> AORN states they have been a major contributor to the creation of the interim statement. 2. From their recommendation above and the Interim Guidance statement they recommended we conduct a risk assessment with Facilities and Infection Control to determine our temperature range in the OR. We completed the Risk Assessment October 14, 2015, prior to our initial submission. 3. Additionally, they recommended we collect data on our operative patients and monitor the monitoring of the temperatures of our patients in the peri-operative phase. We have been collecting this data prior to our initial submission and we are at 100% compliance maintaining our patient's temperature at normothermia per the SCIP/National Hospital Inpatient Quality Measures. (National Hospital Inpatient Quality 	

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S 0612 Bldg. 00	410 IAC 15-1.5-2 INFECTION CONTROL 410 IAC 15-1.5-2(f)(3)(D)(xi) (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:		Measures and Surgical Care Improvement Program –October 16, 2014) Patients are monitored for hypothermia and active patient warming devices are used to maintain normal bodytemperature. We reviewed data on bodytemperature for the patients we serve and were able to confirm thatnormothermia is maintained even with lower ambient room temperatures in the OR.Our data collection to date is 100% normothermia and we have no evidence thatthe lower ambient temperature in our ORs under daily operations have anyadverse impact on surgical care among the patients we serve. January 25, 2016 Request for the submission of the Humidity and Temperature Monitoring and Response Policy	

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	<p>(xi) A program of linen management for personnel involved in linen handling.</p> <p>Based on document review, observation, and interview, the hospital failed to ensure assorted clean linen were stored in a clean and sanitary environment in the Clean Linen Distribution Room.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Saint Joseph Regional Medical Center Linen Use/Bed Change policy (last reviewed April 2014) indicated Linen can be placed on a designated linen-serving cart to be distribution to each room. Cart must be clean and linen must be covered. 2. At 2:20 PM on 9/29/2015, the Clean Linen Distribution room was observed with at least 6 carts uncovered storing assorted clean linen. The ceiling tile above the uncovered carts was observed with peeling paint covering several areas of the ceiling. The paint chips posed a hazard of possibly falling onto the clean lining. 3. At 2:25 PM on 9/29/2015, staff member #8 (Facility/Plant Operation) confirmed the linen needs to be protected from falling material from the ceiling. 	S 0612	<p>Linen storage room</p> <p>The peeling ceiling tiles were replaced the day of survey, 9/29/2015. The ceiling tiles will be monitored and managed during monthly EOC rounds. EOC rounds are reported at the monthly EOC meetings and any findings are reviewed. Materials Management/Laundry staff corrected the deficiency of linens not being covered on 11/3/15. The Linen Room staff were educated to leave plastic wrap over the carts at all times and use re-usable cart covers when needed at AM huddle on November 3, 2015. On 11/4/15, the linen room received 5 re-usable cart covers to be used for any cart that has shipping wrap removed. On 11/4/15 SCM Team Lead and Linen Colleague will monitor clean linen is covered at all times, during transport and storage, and educated in department meeting. Any deficiencies will be reported On 11/5/15 Reminded Linen and Storeroom staff to leave plastic wrap over the carts at all times and use re-usable cart covers when needed at PM huddle 11/10/15 New Process and policy was approved by the Director of Materials Management. 11/11/15 Process communicated with staff in PM huddle. 11/12/15 Process communicated with staff</p>	11/12/2015			

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S 1118 Bldg. 00	<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 document review, observation, and interview, the hospital failed to maintain the hospital environment and equipment in such a manner that the safety and well-being of patients, visitors, and/or staff are assured in one (1) instances: Compressed Gas Storage Room.</p> <p>Findings included:</p> <p>1. Saint Joseph Regional Medical Center Medical Gas Safety Policy (last reviewed April 2014) stated, " All freestanding compressed gas cylinders, whether empty or full, shall be properly secured. "</p>	S 1118	<p>in AM huddle.</p> <p>Gastanks The Director of Facilities is responsible for the oversight of the gas tank storage. The PlantOperations Maintenance Mechanic immediately secured the Nitrogen Compressed gascylinders on the day of survey Sept 28, 2015. The Waste Gases Management Monitoring & Disposing of Hazardous Gasesand Vapors Policy was reviewed with Plant Operations associates during dailyhuddle on 9/30/2015. S Special attention was paid to the storage and handling section. 1)Compressed Gas: a) Tanks of compressed gases will be stored upright andchained or otherwise secured to a support system to minimize fallingover. All Plant Operations Associates were re-educated on 9/30/15.</p>	10/02/2015

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S 1164 Bldg. 00	<p>2. At 2:55 PM on 9/29/2015, the compressed gas storage room was observed storing 3 large Nitrogen Compressed gas cylinders unsecured. The chain for securing the cylinders was observed lying on the floor.</p> <p>3. At 2:57 PM on 9/29/2015, staff member #8 (Facility/Plant Operations) confirmed the 3 gas cylinders were not secured and should have been.</p> <p>410 IAC 15-1.5-8 PHYSICAL PLANT 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:</p> <p>(B) There shall be evidence of preventive maintenance on all equipment. Based on document and interview, the hospital failed to ensure preventive</p>	S 1164	TheMaterials Management staff was educated on 9/30/15. An annual preventative maintenance work order was created for annual education on Medical GasManagement Monitoring and Disposing of Hazardous Gases and Vapors focusing on storage and handling. Random weekly checks are being performed, with logdocumentation monitoring and the results are being placed on the UtilitiesManagement Performance Improvement Trend Report. This will continue to be monitored in 2015 and 2016. The Performance Improvement Trend Report is shared once a quarter at EC/IC Team meetings which in turn is reported to the PerformanceImprovement Steering Committee and to the Quality Committee of the Board.	10/13/2015	

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	<p>maintenance was conducted on wheel chairs.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. Medical Equipment Management Plan (MEMP), last reviewed 7/10/2014, indicated all patient care equipment shall be evaluated through a risk assessment program to set the inspection requirement time frame. 2. The Service Support Matrix of all hospital equipment was reviewed. The matrix indicated the wheel chairs are to be inspected by Plant Operations. The preventive maintenance documentation was reviewed for selected patient care equipment. Clinical Engineering did not conduct a risk assessment for scheduling preventive maintenance inspections on wheel chairs. 3. Saint Joseph Regional Medical Center Wheel Chair Risk Assessment described the annual PM of wheel chairs. 4. At 9:45 AM on 9/29/2015, staff member #12 (Clinical Engineer Director) indicated the wheelchairs are not evaluated through the MEMP program. The staff member indicated the Facility's Operation are responsible for the preventive maintenance of the hospital 		<p>Engineering performed an analysis of the need to perform preventative maintenance on wheelchairs and risk scores deemed wheel chairs were NP (No Preventative Maintenance). A copy of this assessment is attached. Facilities Resources conducted a search of corrective maintenance work orders from 10-5-2005 (date Plymouth Plant Ops began using AIMES) through 10/13/2015 and found the following:</p> <ul style="list-style-type: none"> ·5/30/2006 Work Order 4166 issued & completed. ·5/10/2006 Work Order 3615 issued & completed 5/11/2006. ·35/8/2006 Work Order 2529 issued & completed 3/10/2006. <p>Trinity Health Clinical Engineering (BioMed) has deemed wheel chairs are Non-PM equipment. Facilities Resources searched records from 10-5-2005 when AIMES computerized maintenance system went into effect through 10-13-2015 and only 3 preventative maintenance work orders were entered. A risk assessment was completed by the team based upon the information shared by Trinity Health Clinical Engineering and Plymouth Plant Operations search of corrective maintenance work orders for the last 10 years that annual preventative maintenance is not warranted or necessary. Staff will continue to remove any wheel chair from service that is</p>				

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(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
S 1168 Bldg. 00	<p>wheel chairs. The staff member indicated he she does not have the actual count of the assorted wheelchairs that are used throughout the hospital.</p> <p>5. At 10:45 AM on 9/29/2015, staff member #8 (Facility/Plant Operation) confirmed the hospital did not do a risk assessment on the wheel chairs. The staff member indicated every year the hospital would have a roundup of wheel chairs so they could receive their annual preventive maintenance. However, over half of the wheel chairs are never brought to the roundup. Thereafter, it was decided to repair the wheel chairs as needed due to lack of interest of the annual wheel chair roundup. The staff member confirmed the wheel chairs were never assessed through the Medical Equipment Management Plan's risk assessment.</p> <p>410 IAC 15-1.5-8 PHYSICAL PLANT 410 IAC 150-1.5-8 (d)(3)</p> <p>(d) The equipment requirements are as follows:</p> <p>(3) Defibrillators shall be discharged at least in accordance with</p>		<p>noted to needrepair and place a corrective maintenance work order. The wheelchairs willeither be repaired by Plant Operations or removed from service and replaced with new wheelchairs 1164 Have you removed the wheelchairs from theService Support Matrix or the annual PM of wheelchairs from the RiskAssessment which would indicate the facility is to do an annual PM? Please indicate in the plan ofcorrection that they have been removed if they have. Wheelchairswhich are deemed not repairable are removed from service. Wheelchairs have been removed from the Service Support Matrix based on the riskassessment dated 10/13/2015, see attached document. Based on the riskassessment, wheelchairs are repaired as needed. There is no need for a periodicPM on wheelchairs as they are either repaired as needed in real time ordiscarded if they can't be repaired.</p>	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150076	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED 09/29/2015
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	<p>manufacturers recommendations and a discharge log with initialed entries shall be maintained.</p> <p>Based on document review and interview, the hospital failed to ensure the Zoll M-series Defibrillator, used in Obstetric (OB) and Med/Surg Departments, had no documented evidence of operator's Shift Checklists conducted prior beginning of every shift.</p> <p>Findings included:</p> <ol style="list-style-type: none"> 1. The Zoll M-series Operator's Guide periodic maintenance indicated that resuscitation equipment must be maintained to be ready for immediate use. The operational checks should be performed at the beginning of every shift to ensure proper equipment operation and patient safety. 2. At 1:40 PM on 9/29/2015, the Med/Surg Department was toured. The Crash Cart Log was reviewed for the month of September 2015 and the log indicated that the Zoll M-series defibrillator was checked once per day. 3. At 1:45 PM on 9/29/2015, staff member #18 (Nurse Manager) indicated the defibrillator is checked once a day. The nursing staff operates two twelve 	S 1168	<p>The oversight of the code carts for the organizationis the CNO. The Code Blue policy was reviewed and updated toinclude the once a shift check for the code cart and defibrillators. The codecart log was updated to include both shifts, 7a-7P and 7P-7A. The policy and log were approved at the Nov 6,2015 Team 3/Provision of Care meeting, chaired by the CNO. Staff will be educated in the month of November 2015regarding the updates in the policy, specifically the once a shift check of thecode cart and defibrillator. The education will occur through various methodssuch staff meetings, emails to staff and educational flyers. Education of staff to be completed by December 1, 2015. The code cart logs will be monitored for compliance eachmonth for the next 6 months , followed by random audits. The results of the audits will bereported to Team 3/Provision of Care and reported to the Quality Committee ofthe board.</p>	12/01/2015

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 150076	X2) MULTIPLE CONSTRUCTION A. BUILDING <u>00</u> B. WING _____		X3) DATE SURVEY COMPLETED 09/29/2015
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	hour shifts per day. 4. At 1:55 PM on 9/29/2015, the OB Department was toured. The Crash Cart Log indicated that the Zoll M-series defibrillator was checked once per day for the month of September 2015.				