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PRINTED: 11/30/2015
FORM APPROVED

Office of Inspector General

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 300200	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ <small>OFFICE OF INSPECTOR GENERAL DIVISION OF HEALTH CARE FACILITIES AND SERVICES</small> B. WING: _____	(X3) DATE SURVEY COMPLETED 11/19/2015
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NAME OF PROVIDER OR SUPPLIER EMW WOMEN'S SURGICAL CENTER, PSC	STREET ADDRESS, CITY, STATE, ZIP CODE 136 WEST MARKET STREET LOUISVILLE, KY 40202
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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) COMPLETE DATE
E 000	902 KAR 20:360 Initial Comments A Relicensure Survey was initiated and concluded on 11/19/15 and found the facility not meeting the minimum requirements for relicensure with deficiencies cited.	E 000		
E 245	902 KAR 20:360 Section 5. Administration and Operation a. A person with negative tuberculin skin tests who has direct contact with patients shall have an annual tuberculin skin test. [5.(3)(a)2.a] This requirement is not met as evidenced by: Based on interview and record review, it was determined the clinic failed to ensure all person's with a negative tuberculin skin tests who had direct contact with patients had an annual tuberculin skin test performed and the test results included with the employee's file for four (4) of six (6) files reviewed. The findings include: Review of the Clinic's Policy and Procedure manual revealed there was no written policy in place related to the yearly TB testing that was required for all staff and a procedure in place to monitor and insure that all testing was performed and documented in employee personnel files. Review of the employee files revealed four (4) files did not have mandatory yearly TB testing results listed in files. 1. Interview, on 11/19/15 at 10:21 AM, with Employee #4 revealed she did not know when her last TB was. Review of that employee's file did not produce any evidence of TB testing being performed.	E 245	<u>Written policy related to yearly TB testing:</u> A written policy regarding yearly TB test have been created and has been placed in the Policy and Procedure Manual. This policy reflects that the Director orders the test each year, within 12 months of the most recent test, and assigns a staff nurse to give and read the results. New employees must provide proof of a recent valid test or get a skin test at the EMW clinic prior to starting her/his job.	12-10-15

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: *[Signature]* TITLE: *Exec. Director* (X8) DATE: *12-11-15*

STATE FORM 6899 RDXG11 If continuation sheet 1 of 8

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{E 000}	902 KAR 20:360 Initial Comments Based upon implementation of the acceptable POC, the facility was deemed to be in compliance, 12/10/15 as alleged.	{E 000}		

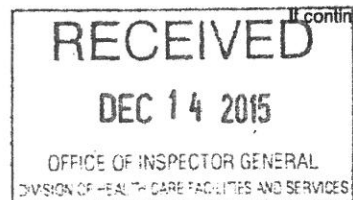
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

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E 245	<p>Continued From page 1</p> <p>2. Interview, on 11/19/15 at 10:30 AM, with Employee #5 revealed she believed her last TB test was probably three (3)years ago.</p> <p>3. Interview and record review, on 11/19/15 at 1:07 PM, with Employee #2 on duty revealed she did not know why her TB test results were not in her file. The last documented TB in her file was 2012. Employee #2 stated her last TB testing was done at a local school of medicine. Evidence of the test and results was provided for 2015 at the time of the survey. No evidence of TB testing for years 2013, or 2014 was provided at time of the survey.</p> <p>4. Review of Employee #6's file revealed TB testing for the years 2013 and 2014 were not located.</p> <p>Interview, on 11/19/15 at 1:07 PM, with the Clinic Director revealed she had no idea why the TB tests were not in the employee files. The Clinic Director was unsure if this was a problem.</p>	E 245	<p><u>TB test results in employee file:</u></p> <p>On 11--25-2015 all employees were given a tuberculin skin test and the results were placed in the employee personnel files</p> <p>The documentation and storage of the yearly tests will be assured by the Clinic Director.</p>	11-25-15
E 330	<p>902 KAR 20:360 Section 5. Administration and Operation</p> <p>6. In-service training programs shall be planned and provided for all employees and volunteers to ensure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individual attendance. The following training shall be provided at least annually:</p> <p>a. Infection control, to include as a minimum, universal precautions against blood-borne diseases, general sanitation, personal hygiene such as hand washing, use of masks and gloves,</p>	E 330		



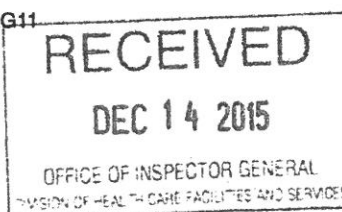
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E 565	<p>Continued From page 3</p> <p>that are not accessible to unauthorized persons. Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements established on the label of medications. A thermometer accurate to + three (3) degrees Fahrenheit shall be maintained in these refrigerators. Only authorized personnel shall have access to storage enclosures. Controlled substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws. [7.(3)]</p> <p>This requirement is not met as evidenced by: Based on observation and interview it was determined the clinic failed to ensure that all medicines and drugs maintained in the facility for daily administration were not expired and were properly stored.</p> <p>The findings include:</p> <p>Observation, on 11/19/15 at 1:33 PM, of the secured medications conducted along with the Clinic Director revealed the medications that were used during the course of the day were not properly stored to prevent access to unauthorized persons. Continued observation revealed there were medications stored in the sterilization room in the bottom of a locked cabinet. The Clinical Director retrieved a key from an unlocked upper cabinet directly above the locked cabinet. Located inside the locked cabinet were (20) twenty, 200 mg/20 ml bottles of Propofol. The locked medication was used daily by the Nurse Anesthetist. The only door leading into the sterilization room did not have the capability to be locked when staff was not in the room and or immediate area.</p> <p>Interview, on 11/19/15 at 11:36 AM, with</p>	E 565	<p><u>Expired medication</u></p> <p>EMW Clinic has a form, with all medications listed, for the purpose of inventory control and expiration date of medicines. Vickey, RN is responsible for assessing these monthly, discarding expired medication, and asking clinic director to order medications as needed. The RN and Director will assure medications are up to date.</p> <p><u>Storage of Medicines</u></p> <p>EMW stores medicines that are used on a daily basis in locked refrigerator and cabinets in pre-op and post-op rooms. Nurses have kept keys to these cabinets in a drawer in the room due to the fact that once our patients and staff have left the building it is locked and an alarm system secures the building. Since our recent inspection, we are keeping the</p>	<p>11-25-15</p> <p>11-24-15</p> <p>cont.</p>
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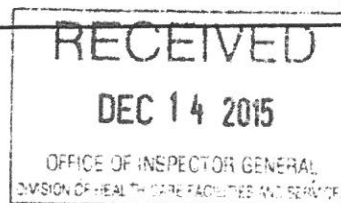
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E 565	<p>Continued From page 4</p> <p>Registered Nurse (RN) #3 revealed the Clinic Director always had the key to the lockbox for the Valium that the RN administers to patients if needed. On 10/19/15 there was no access to the Valium at the time of request to inspect the contents of the lockbox due to the Clinic Director was not in the clinic. The Medical Doctor did not have access to the controlled drug at this time.</p> <p>Interview, on 11/19/15 at 1:33 PM, with the Clinic Director revealed she had always kept the key to the Valium storage cabinet hidden in her office in a desk drawer. The Director instructed staff in the front office where the key was in case the key to the double locked cabinet/box was needed in her absence.</p> <p>Interview with Employee #4, on 11/19/15 at 8:15 AM, revealed the Clinical Director was not in the clinic on this date and would not be coming into the office. The staff did not have access to any policy and procedures at the time of this survey. A call was made to the Clinical Director by Employee #4 to inform her of the survey. The Director stated she would not be coming in to the Clinic this date due to her going to the airport to pick up her son. The Director stated there was a binder with policies and procedures in the clinic, but it was locked up in her office and nobody had access except her.</p> <p>Interview, on 11/19/15 at 1:33 PM, with the Clinical Director revealed the key to the locked cabinet that contained the medication Propofol was always kept in the unlocked cabinet located directly above the locked cabinet. Having the key in this location allowed anyone to gain access to any of the locked medications.</p>	E 565	<p>keys in a locked room, the Director's office, where the nurses can retrieve the keys in the morning and give to the Director to store them overnight. In the Director's absence she will delegate the possession of the key to a nurse.</p> <p><u>Storage of Propofol</u></p> <p>Propofol is used by the Nurse Anesthetist only and a running log of its use and distribution is kept by the CRNA and Clinic Director. The key to the locked cabinet has since inspection been removed from the upper cabinet and is being kept in the Director's locked office. In her absence the keys are given to the CRNA.</p> <p><u>Keys to Valium Cabinet.</u></p> <p>Two 5 mg Valium tablets are given to our patients for local anesthesia. This happens once every 2 months as most patients prefer general anesthesia. The keys to the double locked Valium cabinet</p>	<p>11-24-15</p> <p>11-24-15</p> <p>Cont.</p>
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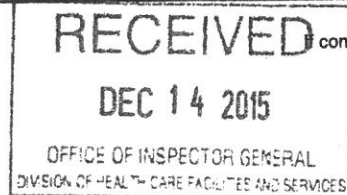


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E 650 E 650	<p>Continued From page 5</p> <p>902 KAR 20:360 Section 9. Medical Waste Disposal</p> <p>(2) Disposable waste. (a) All disposable waste shall be placed in suitable bags or closed containers so as to prevent leakage or spillage, and shall be handled, stored, and disposed of in such a way as to minimize direct exposure of personnel to waste materials. [9.(2)(a)] This requirement is not met as evidenced by: Based on observation and interview, it was determined the clinic failed to ensure all disposable waste was placed in suitable bags or closed containers to prevent leakage and stored in such a way as to minimize direct exposure of personnel to waste materials.</p> <p>The findings include:</p> <p>Observation, on 11/19/15 at 12:11 PM, revealed a treatment room with one (1) full, all the way to the top past the fill line, sharps container with a dark brown substance splattered on the entire top of the sharps container. An empty/unused sharps container was on the floor under a cabinet in plain view.</p> <p>Interview, on 11/19/15 at 12:11 PM, with RN #3, revealed the dark brown substance on the top of the sharps container was dried blood. RN #3 stated this was not the proper way to discard sharps material and that the blood on top of the container could possibly cause exposure to any blood borne pathogens. RN #3 stated she was not aware the sharps container had not been removed or replaced with an empty one and she had no knowledge of the condition of the top of the sharps container. RN #3 stated HIV, Hepatitis, and any vaginal infectious diseases may be present in the blood on top of the sharps</p>	E 650 E 650	<p>are always in the Director's possession and she gives them to the nurses as they need them and are no longer kept hidden in her desk drawer, but rather in a the Director's locked office. In the Director's absence the keys are given to a nurse.</p> <p><u>Medical Waste Disposal</u></p> <p>The employee in the lab has been instructed to assure that the sharps container does not get filled past the fill line. She has been asked to clean the top of the container when leaving the lab so it is free of dried blood splatter. The Director will assure this happens every day.</p>	11-20-15

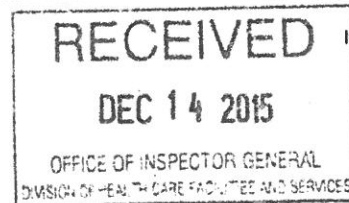


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E 650	<p>Continued From page 6</p> <p>container.</p> <p>Interview, on 11/19/15 at 12:13 PM, with the Medical Doctor (MD) revealed the dark brown substance on the top of the sharps container was dried blood. The MD stated this was not the proper way to discard sharps material and that the blood on top of the container could possibly cause exposure to any blood borne pathogens. The MD stated HIV, Hepatitis may be present in the blood on top of the sharps container.</p> <p>Observation with the MD, Clinic Director, and RN #3, on 11/19/15 at 12:34 PM, revealed located in the common area in the hallway across from the sterilization room was an uncovered trash can. Inside the trash can, in plain view, were four (4) needleless syringes. Two (2) of the four (4) needleless syringes had a white milky substance.</p> <p>Interview, on 11/19/15 at 12:34 PM, with RN #3 revealed she identified the medication as Propofol. The RN stated this medication was used earlier in the day for a procedure that was performed. RN #3 stated this was not the proper way to dispose of the medical waste and it should have been put in a sharps container.</p> <p>Interview, on 11/19/15 at 12:34 PM, with the MD revealed she identified the medication as Propofol. The MD stated this medication was used earlier in the day for a procedure that was performed. The MD stated this was not the proper way to dispose of the medical waste and it should have been put in a sharps container.</p> <p>Interview, on 11/19/15 at 12:34 PM, with the Clinic Director revealed she identified the white milky substance in the needleless syringes as Propofol. The Clinic Director stated this was not the proper</p>	E 650	<p><u>Propofol Syringes</u></p> <p>The CRNA has been instructed not to discard syringes in the trash. They are now being disposed of in a sharps container. The Director is assuring the syringes are placed in sharps containers.</p>	11-20-15



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E 650	Continued From page 7 way to dispose of the medical waste and it should have been put in a sharps container.	E 650		
E 730	<p>902 KAR 20:360 Section 11. Equipment and Supplies</p> <p>There shall be appropriate equipment and supplies maintained for the patients to include:</p> <p>(9) Containers for soiled linen and waste materials with covers; [11.(9)] This requirement is not met as evidenced by: Based on observation and interview, it was determined the facility failed to ensure there were appropriate containers with covers for soiled linen and waste materials.</p> <p>The findings include:</p> <p>Observation, on 11/19/15 at 12:15 PM, revealed a soiled bed sheet and wash cloth hanging off the side of an uncovered soiled linen cart.</p> <p>Interview, on 11/19/15 at 12:15 PM, with RN #3 revealed the soiled linen should have been placed in a yellow plastic bag and then tied and placed in the soiled linen cart. RN #3 stated exposure to soiled lined was a problem because of infection control.</p> <p>Interview, on 11/19/15 at 12:20 PM, with the MD revealed the soiled linen should have been placed in a yellow plasitic bag and then tied and placed in the soiled linen cart. The MD stated exposure to soiled lined was a problem because of infection control.</p>	E 730	<p><u>Soiled Linen</u></p> <p>The Orderly has been asked to make sure all soiled linens are immediately placed in yellow plastic bags, tied and placed in the soiled linen cart. The Director is making sure this method is adhered to.</p>	11-20-15

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DIVISION OF HEALTH CARE FACILITIES AND SERVICES



**CABINET FOR HEALTH AND FAMILY SERVICES
OFFICE OF INSPECTOR GENERAL**

Matthew G. Bevin
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Vickie Yates Brown Glisson
Secretary

Stephanie Hold
Acting Inspector General

January 4, 2016

Ms. Anne Ahola, Administrator
EMW Women's Surgical Center, PSC
136 West Market Street
Louisville, KY 40202

Dear Ms. Ahola:

The Division of Health Care received your plan of correction pertaining to the deficiencies identified during the state survey completed on November 19, 2015. This office has accepted your plan of correction. Upon review of your plan of correction, it was determined that implementation of this plan should result in compliance with minimum licensure requirements.

If you have any questions, please contact our office.

Sincerely,

A handwritten signature in cursive script that reads "Millie K. Zumstein".

Millie K. Zumstein, R.D., L.D.
Regional Program Manager
Division of Health Care

MKZ/ror

Enclosure