7/10/12 POC accepted
x [illegible]

PRINTED: 06/21/2012
FORM APPROVED

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070000149	A. BUILDING ______ B. WING ______	C 04/27/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SANTA CLARA VALLEY MEDICAL CENTER	751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128

(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	Initial Comments The following reflects the findings of the California Department of Public Health during the investigation of two entity reported incidents completed on 4/27/12. For Entity Reported Incidents CA00305893 and CA00305889 regarding Quality of Care/ Treatment -- Patient Safety, two State deficiencies were identified (see California Code of Regulations, Title 22, Section 70263(g)(2) and Health & Safety Code 1280.1(c)). Inspection was limited to the two entity reported incidents investigated and does not represent the findings of a full inspection of the hospital. Representing the California Department of Public Health was 28767, Health Facilities Evaluator Nurse. Health and Safety Code1280.1 (c), for purposes of this section "Immediate Jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY	E 000	CALIFORNIA DEPARTMENT OF PUBLIC HEALTH JUL - 6 2012 L & C DIVISION SAN JOSE	
E 485	T22 DIV5 CH1 ART3-70263(g)(2) Pharmaceutical Service General Requirements (g) No drugs shall be administered except by licensed personnel authorized to administer drugs and upon the order of a person lawfully authorized to prescribe or furnish. This shall not preclude the administration of aerosol drugs by respiratory therapists. The order shall include the	E 485		

Licensing and Certification Division

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Judy Johnson Interim CEO
TITLE
(X6) DATE 7/5/12

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070000149	A. BUILDING _____ B. WING _____	C 04/27/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SANTA CLARA VALLEY MEDICAL CENTER	751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128

(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 485	Continued From page 1 name of the drug, the dosage and the frequency of administration, the route of administration, if other than oral, and the date, time and signature of the prescriber or furnisher. Orders for drugs should be written or transmitted by the prescriber or furnisher. Verbal orders for drugs shall be given only by a person lawfully authorized to prescribe or furnish and shall be recorded promptly in the patient's medical record, noting the name of the person giving the verbal order and the signature of the individual receiving the order. The prescriber or furnisher shall countersign the order within 48 hours. (2) Medications and treatments shall be administered as ordered. This Statute is not met as evidenced by: Based on interview and record review, the hospital failed to administer medication as ordered for two of two sampled patients (1 and 2). The failure resulted in the patients receiving 16.6 times more than the intended dose of chemotherapy medication (methotrexate). A pharmacy technician failed to dilute the medications with normal saline as ordered by the physician. A pharmacist failed to ensure the medications were prepared correctly by the pharmacy technician. The pharmacist failed to implement the hospital's policies and procedures for the preparation of admixtures (medication produced by mixing). The patients suffered adverse reactions including seizures, and required increased levels of care. The dispensing of high concentrations of methotrexate was likely	E 485		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070000149	A. BUILDING _____ B. WING _____	C 04/27/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SANTA CLARA VALLEY MEDICAL CENTER	751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128

(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 485	Continued From page 2 to cause serious injury or death to a patient. Findings: Patient 1 was admitted to the hospital on [redacted]/12 with diagnoses including breast cancer. Patient 2 was admitted to the hospital on [redacted]/12 with diagnoses including B-cell lymphoma (cancer that forms in B cells) of the brain. Physician A (PH A) was the oncologist for both patients. On 4/24/12 a review of PH A's medication orders dated [redacted]12 for Patient 1 and Patient 2 indicated each patient was to receive 12 milligrams (mg) of preservative free methotrexate (medication used to treat certain types of cancer) in 8 cubic centimeter (cc) of normal saline (diluent) to be administered intrathecal (directly into the spinal fluid) by physician. During an interview on 4/24/12 at 10 a.m. with the pharmacy director, he stated the pharmacy received the above order via fax on [redacted]12. As per standardized procedure for oncology medications two pharmacists (pharmacist A and pharmacist B), independent of each other, reviewed the medications orders to ensure the orders had the appropriate medication dosages for the patients' profiles. The medication orders for both Patient 1 and Patient 2 were appropriate and labels were printed indicating how to prepare the medications. The pharmacy director further stated pharmacy technician A (PT A) received the medication labels and proceeded to prepare the medications for administration. Methotrexate is commercially available as 25 milligrams per cc (mg/cc). During	E 485	**CORRECTIVE ACTIONS FOR PATIENTS** 1. Physician notified the patients and families regarding these events. 2. Patient 1 was transferred to a higher level of care. Patient 1 was given lorazepam for mild seizure activity, leucovorin and dexamethasone for reversal of methotrexate toxicity. Seizure activity ceased. Symptoms due to methotrexate completely resolved. Patient 1 recovered and was discharged. 3. Patient 2 was intubated and transferred to the intensive care unit. Patient 2 was continued on anticonvulsant medication. Leucovorin and dexamethasone doses were increased for reyersal of methotrexate toxicity. Seizure activity ceased. Symptoms due to methotrexate resolved. Follow up MRI showed improvement in CNS lesion. Patient 2 recovered and was discharged. **IMMEDIATE MEASURES AND SYSTEM CHANGES TO MITIGATE REOCCURRENCE** 1. A system improvement was instituted immediately: A "Production Label" was instituted for all chemotherapy and intrathecal compounded products. The production label will be completed by the pharmacist and requires the following documentation for each intrathecal and chemotherapy admixture:	[redacted]/2012 [redacted]/2012

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070000149	A. BUILDING _____ B. WING _____	C 04/27/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SANTA CLARA VALLEY MEDICAL CENTER	751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128

(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 485	Continued From page 3 preparation of both medications, PT A withdrew 8 cc (200 mg) of undiluted methotrexate into a syringe, instead of 0.48 cc (12 mg), 16.6 times the doses prescribed. Pharmacist C was assigned to verify the medications were prepared correctly by PT A. Pharmacist C assumed PT A had withdrawn the correct amount of medications (0.48 cc) and had diluted the medications in 7.52 cc normal saline. Without confirming the medications were prepared correctly, Pharmacist C approved the medications prepared by PT A. Both Pharmacist C and PT A initialed the labels indicating the medications were prepared as ordered. The chemotherapy medications were later administered to Patient 1 and Patient 2 by Physician A. On 4/24/12 at 10:30 a.m., review of the pharmacy labels for Patient 1 and Patient 2's medication orders indicated: sodium chloride 0.9% (normal saline) 8 cc, methotrexate sodium 12 mg, intrathecal use only, and "MD to administer". On the above date and time, when asked to explain the medication labels, the pharmacy director stated the above order meant to dilute 12 mg of methotrexate in normal saline. After the mixture there would be a total of 8 cc of fluid in each syringe. According to the pharmacy director, the pharmacy had a process where pictures of medication, diluent, syringes, labelling, etc., were taken before and after chemotherapeutic medication compounding. On 4/24/12 at 10:40 a.m. a review of the medication pictures for Patient 1 and Patient 2 was conducted with the pharmacy director. The first colored picture taken on [redacted]/12 at 12:25 included a 40 cc bottle of methotrexate indicating each cc contained 25	E 485	a. The drug, concentration of the stocked vial, and the amount/volume needed. b. The diluent and the amount/volume needed. c. Signatures of the two pharmacists who filled and checked the production label against the order. All inpatient pharmacy staff was inserviced on this process. 2. All Inpatient Pharmacy staff underwent the annual competency skills assessment for preparation and compounding of intrathecal medications. The training emphasized drug dilution and drug concentrations. 3. The technician will be disciplined for not following the procedure for the compounding the intrathecal methotrexate. The technician was retrained and has successfully completed follow-up competency. 4. The pharmacist was disciplined for not following procedure for pharmacist review and not providing appropriate supervision to the technician. The pharmacist was retrained and has successfully completed follow-up competency. 5. The P&T Committee Coordinator informed all Oncology physicians (including OB/Gyn oncologists) that they must write chemotherapy orders at least 24 hours before chemotherapy is to be compounded. No "STAT chemotherapy" orders will be accepted (with the exceptions of ectopic pregnancy and acute myeloid leukemia).	5/10/2012 7/9/2012 6/29/2012 6/4/2012 6/26/2012 4/17/2012

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070000149	A. BUILDING _____ B. WING _____	C 04/27/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SANTA CLARA VALLEY MEDICAL CENTER	751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128

(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 485	Continued From page 4 milligrams of methotrexate (25 mg/cc), and two syringes each filled with 8 cc of fluid matching the fluid inside the methotrexate bottle. The second colored picture taken on [redacted]/12 at 12:27 included the same medication bottle and the two syringes filled with 8 cc of fluid matching the fluid inside the medication bottle. The only exception between the first and second pictures was in the second picture, each syringe had a label indicating there was 12 mg of methotrexate diluted in 8 cc of normal saline. During review of the above pictures, the pharmacy director stated the pictures lacked a bottle of normal saline, indicating normal saline was not used for the preparation of the medications. On 4/24/12 at 12 p.m. during an interview with Pharmacist C, he stated that he was informed by the other pharmacist on duty that the medications for Patient 1 and Patient 2 needed to be ready for physician pick up. Pharmacist C was responsible to ensure PT A had prepared the medication correctly. Pharmacist C stated he looked at the pharmacy labels and noted there should be a final volume of 8 cc's in each syringe. He ensured the medications were preservative free and assumed PT A had already diluted the medications with normal saline. He did not question PT A regarding the dilution of the medication. Pharmacist C stated both he and PT A initialed the labels and attached the labels to the syringes with the medications. On 4/24/12 at 12:30 p.m., during an interview with PT A she stated she was interrupted from her assigned duties to prepare the above medications because they needed to be ready for pick up. PT A stated she got the preservative free methotrexate, looked at the expiration date, and withdrew 8 cc of the medications into each of two	E 485	**QUALITY REVIEW / PERFORMANCE MONITORING PROCESS** 1. Inpatient Pharmacy Manager/Medication Safety Coordinator will audit the new production label process for 100 admixtures for thirty (30) days. The audit will include checking the production label for each chemotherapy product to ensure the label was filled correctly including the drug/concentration of the stocked vial and the amount/volume needed, the diluent and the amount/volume needed, and the signatures of the two pharmacists who filled and checked the production label against the order. After 100% compliance for 30 consecutive days, 30 admixtures per month will be observed for three (3) months and results reported to the Medication Safety, Pharmacy & Therapeutics (P&T), Patient Safety, and Medical Executive Committees. If issues are discovered during this period, monitoring of 30 admixtures per month will be continued until 100% compliance is achieved for three (3) consecutive months. 2. Inpatient Pharmacy Manager/Medication Safety Coordinator will audit 30 patient charts each month for three (3) months to ensure that chemotherapy orders are not rushed and appropriate timeframes are followed for written chemotherapy orders. A report detailing any exceptions or issues will be reported to the Medication Safety Committee and the P&T Committee. If issues are discovered during this period, monitoring of 30	5/1/2012 5/1/2012

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070000149	A. BUILDING _____ B. WING _____	C 04/27/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SANTA CLARA VALLEY MEDICAL CENTER	751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128

(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 485	Continued From page 5 syringes. PT A stated she was aware the methotrexate was going to be administered intrathecaliy (injected into the spine). PT A further stated it was her second time preparing methotrexate for intrathecal use and did not know it needed to be diluted. PT A stated she felt rushed and overlooked the information on the label and on the bottle indicating to dilute the medication in normal saline. The hospital's policy and procedures regarding "admixtures" dated 4/12 indicated a pharmacist should "check all work done by the technicians" and inspect the completed admixture for accuracy. Review of the hospital's policy and procedures regarding "Intrathecal Methotrexate Administration Guidelines" dated 3/09 indicated the maximum dose of 15 mg of Methotrexate is not recommended due to causing neurotoxicity (toxic or poisonous to the nervous system). Policy also indicated "only preservative-free methotrexate diluted with preservative-free 0.9% Sodium Chloride Injection, USP (normal saline), should be used for intrathecal administration." On 4/26/12 at 2:30 p.m. a review of Patient 1's progress notes dated [redacted]/12 at 3:15 p.m. indicated Physician A administered methotrexate to Patient 1. On 4/26/12 at 2:40 a review of the nurse's notes for Patient 1 notes dated [redacted]/12 at 6 p.m. indicated Patient 1 was "not responding" and twitching was noted in her hands and legs. At 6:30 p.m. the rapid response team (quick response to a medical emergency by trained	E 485	admixtures per month will continue until 100% compliance is achieved for three (3) consecutive months.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070000149	A. BUILDING _____ B. WING _____	C 04/27/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SANTA CLARA VALLEY MEDICAL CENTER	751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128

(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 485	Continued From page 6 hospital personal) was called. On 4/26/12 at 3 p.m. a review of Patient 1's Rapid Response note dated [redacted]/12 at 7:30 p.m. indicated that at 7 p.m. the patient was found "drowsy but responsive to name-calling. Right arm was mildly rigid with some twitching movement". Patient 1 received Ativan (tranquilizer) "due to concerns for seizure" and was transferred to the intensive care unit. On 4/26/12 at 3:20 p.m. a review of Patient 1's discharge summary indicated the patient "received higher dose than intended of intrathecal methotrexate on the afternoon of [redacted]/12 due to medication error". The note further indicated Patient 1's "symptoms due to methotrexate completely resolved" and was discharged home on [redacted]/12 under hospice care. On 4/27/12 at 8 a.m., a review of the physician's orders for Patient 2 indicated Physician A administered methotrexate to Patient 2 on [redacted]/12 at 2:40 p.m. On 4/27/12 at 8:15 a.m. a review of the nurse's notes for Patient 2 dated [redacted]/12 at 5:25 p.m. indicated the patient was "having seizures for 10 seconds followed by generalized body jerky movement" and a code blue (cardiac arrest) was called. On 4/27/12 at 8:40 a review of Patient 2's "cardio-pulmonary arrest sheet" dated [redacted]/12 at 5:38 p.m. indicated the patient had to be intubated (placement of a flexible tube into the windpipe to maintain an open airway) and was transferred to the intensive care unit. On 4/27/12 at 9 a.m., a review of Patient 2's	E 485		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	CA070000149	A. BUILDING _____ B. WING _____	C 04/27/2012

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SANTA CLARA VALLEY MEDICAL CENTER	751 SOUTH BASCOM AVENUE SAN JOSE, CA 95128

(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 485	Continued From page 7 discharge summary indicated Patient 2's hospital course was complicated by "supratherapeutic (above the therapeutic level) dosing of MTX (methotrexate) and seizure activity for which she was intubated for airway protection sedated and monitored in the iCU (intensive care unit) for [redacted]". On 4/27/12 at 10 a.m. a review of Lexi-Comp (a national recognized drug information resource) pharmaceutical information indicated high doses of methotrexate may cause acute kidney failure, potentially fatal dermatologic reactions, and liver failure. General symptoms of methotrexate intrathecal overdosage include headache, nausea, vomiting, and seizures. The pharmacy failed to provide adequate oversight of the pharmacy technician and to implement effective policies and procedures for medication preparation and dispensing. As a result, the hospital failed to administer medication as ordered. This failure caused, or was likely to cause, serious injury or death for the patients, therefore, constituting an immediate jeopardy within the meaning of Health and Safety Code, Section 1280.1(c).	E 485		