CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050515	A. BUILDING _____ B. WING _____	11/07/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Kaiser Foundation Hospital - San Diego	4647 Zion Ave, San Diego, CA 92120-2507 SAN DIEGO COUNTY

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	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00374224 - Substantiated Representing the Department of Public Health: Surveyor ID # 28183, HFEN The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.1(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. The following reflects the findings of the California Department of Public Health during the investigation of complaint # CA00374224. The investigation was limited to the specific complaint investigated and does not represent the findings of a full inspection of the facility. Representing the California Department of Public Health: Health Facilities Evaluator Nurse #28183. Health & Safety Code Section 1279.1 (a) (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an		Preparation and submission of this Plan of Correction does not constitute an admission or agreement by Kaiser Foundation Hospital-San Diego (the "Hospital") of the truth of the facts alleged or the conclusions set forth in the Statement of Deficiencies. The Hospital is submitting this Plan of Correction as required by state and/or federal regulations. This Plan of Correction documents the actions by the Hospital to address the alleged deficiencies. This Plan of Correction constitutes credible evidence of compliance with the cited regulations. [Plan of Correction begins on page 5.]	

Event ID: L5BR11 11/12/2014 7:30:26AM

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

Sr VP Exec Dir KFH/HP San Diego 12/4/14

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 8

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. Except for nursing homes, the findings 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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adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

Health & Safety Code Section 1279.1

(b) For purposes of this section, "adverse event" includes any of the following:

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

(d) "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

Health and Safety Code Section 1279.1 (c)

(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

The CDPH verified that the facility informed the patient, or the party responsible for the patient, of the adverse event by the time the report was made.

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Health and Safety Code Section 1280.1

(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

California Code of Regulations, Title 22, Division 5, Chapter 1, Planning and Implementing Patient Care

70215(b) The planning and delivery of patient care shall reflect all elements of the nursing process: assessment, nursing diagnosis, planning, intervention, evaluation and, as circumstances require, patient advocacy, and shall be initiated by a registered nurse at the time of admission.

California Code of Regulations, Title 22, Division 5, Chapter 1, Intensive Care Newborn Nursery Service General Requirements

70483(b) There shall be written policies and procedures developed and maintained by the person responsible for the service in consultation with other appropriate health professionals and administration. Procedures shall be approved by the medical staff and administration where such is appropriate. Such policies and procedures shall include but not be limited to:

(2) Admission to the intensive care

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newborn nursery.

(17) Routine and special care of the infant.

Based on interview and record review, the facility failed to assess and intervene as it related to temperature monitoring and safe settings of an infant radiant warmer. As a result, a premature newborn (Patient 1) was placed under an unregulated radiant heat warmer after birth, suffered a temperature spike to 107.2°F (Fahrenheit), as well as partial burns (known as a second degree burn, which affects the top two layers of skin, the epidermis and hypodermis) and full thickness burns (known as a third degree burn, which involves destruction of the entire skin, extending into subcutaneous tissue, muscle, or bone) to the groin and thigh area.

The facility also failed to report the adverse event to the California Department of Public Health (CDPH) after the adverse event had been detected.

Findings:

During an interview on 10/31/13 at 2:30 P.M. the Director of Regulatory Affairs (DRA) stated that the incident was not reported to CDPH because the facility did not consider the burns to Patient 1 a "serious disability."

The clinical record was reviewed with the DRA on 10/31/13. Patient 1 was born on 10/9/13 at 11:18 A.M. by Cesarean section. The baby was born

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	premature at 24 weeks and weighed 510 grams (1 pound) at birth. Patient 1 was then admitted to the Neonatal Intensive Care Unit (NICU). According to the NICU vital signs record, the first temperature documented of Patient 1 after birth was 96.8°F axillary (under the arm) at 12:01 P.M. Staff documented that the newborn was under the radiant warmer. At 1 P.M., the patient's temperature was unchanged at 96.8°F axillary. There was no temperature documented for another 2 hours, when at 3:15 P.M. the patient's temperature was 107.2°F, still under the radiant heat warmer. At 3:36 P.M., the patient's temperature was still elevated at 102.4°F. The next documented temperature was one hour later, at 4:35 P.M. when it returned to normal 98.2°F. Four days after Patient 1 was born, according to a Family Conference Note, dated 10/13/13, the physician explained to Patient 1's parents that, "The groin which appeared to be typical bruising and edema (fluid retention/swelling) combined with poor perfusion (blood flow to a region, organ, or tissue) in a 24 week infant now appeared to be a burn likely from the heating element of the isolette (self-contained incubator that provides controlled heat, humidity and oxygen for the care of premature or low birth weight newborns)..." A burn specialist physician was consulted and documented on 10/15/13 that Patient 1 had, "Partial thickness burns to right knee, pubic region and labial area." On 10/29/13, according to the progress note by the burn specialist, "She had a		22 CCR 70215(b) & 22 CCR 70483(b) **Immediate and Permanent Corrections** 1. Daily Huddle Message and Other Communications to Staff For a two-week period immediately after this event, the huddle message at each shift change in the Neonatal Intensive Care Unit ("NICU") included a discussion of: (1) the importance of placing the temperature probe when using the Giraffe Omni Bed; (2) the importance of ensuring a safety stop at the time an infant is admitted to the NICU; and (3) a review of the procedures set forth in Policy PCS 12.01.03 (Admission Procedure to Neonatal Intensive Care Unit (NICU) for the Nursing Staff). Further, information highlighting patient safety was posted on the NICU conference room's bulletin board, and a reminder to check temperature probe placement as part of hourly rounding was written on the conference room's white board.	11/01/13

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	burn to the anterior torso, medial/anterior bilateral thighs and perineum. This was due to a heating lamp." The physician further documented, "All of the burn wounds were partial thickness except the perineum (area between the anal and vaginal openings) which is a full thickness injury to both labia (folds of skin surrounding the vaginal opening) tissue...and in the process of liquefactive necrosis" (dead tissue that becomes a liquified). On 11/14/13 at 2 P.M., Registered Nurse (RN) 1 stated during an interview that she received Patient 1 upon admission to the NICU. Per RN 1, she did not put the temperature probe on the baby right away. RN 1 stated, "I had set the radiant warmer to 50% output while in manual mode." According to RN 1, about 3 1/2 hours after admission, she took Patient 1's axillary temperature and it was 107.2°F. RN 1 shut off the warmer and saw the temperature probe sensor on the bed, not on the baby, and the radiant warmer still in manual mode. However, RN 1 was unable to recall if any visual or audible alarms had gone off. During an interview on 11/14/13 at 3 P.M., the Director of Maternal/Child Services (DMCS) stated that the manual mode uses a continuous heat source from the radiant warmer set as a percentage by the nurse. The temperature probe does not communicate in this mode, but displays the baby's temperature. In the baby mode, the radiant warmer is controlled by the baby's temperature through a sensor probe on the baby's skin. According to the DMCS, the radiant warmer setting		**Immediate and Permanent Corrections cont.** 2. Inservice training The nurse caring for the patient at admission conducted an in-service training entitled "Admission of 24 week Low Birth Weight Infant," for the majority of the NICU staff, over multiple sessions in November and December, 2013. In addition to a powerpoint presentation, the following handouts were provided: (1) a Joint Commission Sentinel Event Alert entitled "Behaviors that undermine a culture of safety"; (2) a Permanente Journal article entitled "Elimination of Admission Hypothermia in Preterm Very Low-Birth-Weight Infants by Standardization of Delivery Room Management"; and (3) an article entitled "How to Overcome Task Saturation for Flawless Execution." 3. Policy Revision Clarifying revisions were made to policy PCS 12.01.03 (Admission Procedure to Neonatal Intensive Care Unit (NICU) for the Nursing Staff), in order to reconcile the policy with the user manual for the radiant warmer bed.	12/05/13 02/2014

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	was in manual mode for continuous radiant heat upon Patient 1's admission to the NICU. The DMCS stated that the setting should have been changed to baby mode, using the temperature probe on the baby to regulate the warmer. When Patient 1's temperature was found to be 107.2°F, the setting was not in baby mode but still in manual mode, so heat "was just coming out." On 1/22/14 at 1:45 P.M., RN 2, a staff nurse in the NICU caring for a patient in the same isolette as Patient 1, was interviewed regarding the radiant warmer. According to RN 2, there is an alarm function in manual mode after the radiant warmer has been on for a period of time. There is an audible alarm and visual alarm that activates "Check baby" on the screen. According to the manufacturer's instructions for the incubator/radiant warmer bed, "When operating as a radiant warmer...the manual mode requires constant attention. In the manual mode, you must take the responsibility for detecting changes in the environment or the patient condition requiring heater adjustments in response to these changes." The manufacturer's instructions further indicated, "When the unit is in the manual mode, the Check Baby alarm activates when the radiant heaters preheat power percentage has been exceeded for more than twelve minutes." According to the facility's policy Admission Procedure to Neonatal Intensive Care Unit (NICU) for the Nursing Staff, dated 9/12, "Temperatures of		**Immediate and Permanent Corrections cont.** 4. Specific Training on Use of the Radiant Warmer - Current Staff The active NICU nursing staff viewed the Temperature Probe Application and Control Giraffe Omni Bed Inservice Video and reviewed Policy PCS 12.01.03 (Admission Procedure to Neonatal Intensive Care Unit (NICU) for the Nursing Staff).	04/15/14
			5. Policy Revision Policy PCS 12.19.02 (Staffing for Neonatal Intensive Care Unit (NICU)) was revised to include a 2:1 (nurse:patient) staffing ratio for situations involving infants in certain extremely high-risk situations, including those in the first eight hours of therapeutic hypothermia and the first eight hours of any re-warming period.	04/2014
			Continued Compliance/Monitoring 1. Specific Training on Use of the Radiant Warmer - All New Staff All new nursing employees who may be assigned NICU responsibilities are required to view the Temperature Probe Application and Control Giraffe Omni Bed Inservice Video and review specific written information about the use of the bed.	04/15/14 and Ongoing

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	all patients will be maintained within a neutral thermal environment." In addition, "Radiant warmer bed turned on to servo control (baby mode), temperature probe and adhesive probe cover attached...Check that servo control (baby mode) of warmer is set at 36.5-37.0° Celsius (97.7-98.6°F); and control set to skin." The policy further indicated, "Continue nursing assessment every 15 minutes until stable." The facility failed to assess, evaluate and intervene to provide safe settings and temperature monitoring for a patient under an infant radiant warmer in violation of sections 70215(b) and 70483(b). The facility's noncompliance with these requirements, jointly, separately or in any combination, has caused, or is likely to cause serious injury or death to the patient, and therefore, constitutes an immediate jeopardy within the meaning of the Health and Safety Code Section 1280.1(c). This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).		**Continued Compliance/Monitoring cont.** 2. Chart Audit and Admit Observation The NICU Nurse Manager audited 30 charts per month for March-May, 2014 and 17 charts for June, 2014 (all of the NICU admissions for that month) to ensure documentation of: (1) vital signs as ordered by physician or per policy; (2) Giraffe Omni Bed temperature settings; and (3) physician notification as appropriate. In addition, the NICU Nurse Manager or her designee observed all admissions for that period to ensure staff compliance with the use of the temperature settings and proper location of the temperature probe for the Giraffe Omni Bed. 3. Competency Assessment The proper use of the Giraffe Omni Bed will be reviewed at each annual NICU Competency Program, which is mandatory for all NICU employees. **Person(s) Responsible for all Corrections and Monitoring** NICU Nurse Manager and Director of Maternal Child Health.	06/30/14 12/2014 and Annually Thereafter