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
	050701	A BUILDING ______ B WING ______	11/05/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SOUTHWEST HEALTHCARE SYSTEM	25500 MEDICAL CENTER DRIVE, MURRIETA, CA 92562 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED 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

The following reflects the findings of the California Department of Public Health during a complaint investigation conducted October 28, 2009 The Southwest Healthcare System is comprised of two hospitals under the same licensure (Inland Valley Medical Center and Rancho Springs Medical Center)

Complaint Number CA00206439

Representing the Department of Public Health.

[redacted] HFEN,
[redacted] HFEN, and,
[redacted] HFEN

The Department was able to substantiate a violation of the regulations

On October 29, 2009, at 6:20 p.m., the CEO, COO, Director of Quality Outcomes, and Associate Administrator, were notified a serious and immediate threat to the health and safety of Patients 1, 2, and 3, as well as their babies, and the mothers and babies in the surrounding areas, was identified. The serious and immediate threat was due to the performance of three elective CSs in the OB CS room at RSMC while the recorded humidity in the room was low, creating a risk for a fire to start during the procedures

Abbreviations used in this document:

CEO - Chief Executive Officer

Preparation and submission of this Plan of Correction does not constitute an admission or agreement by Southwest Healthcare System (the Hospital) of the truth of the facts alleged or conclusions set forth in the Statement of Deficiencies. The Hospital is submitting this Plan of Correction as required by state regulations. This Plan of Correction documents the actions taken by the Hospital to address the alleged deficiencies.

A. Administration determined that the three cited patients had their C-sections completed already, so corrective action would not affect them. — 11/05/09

B. Administration identified that humidity below the allowed minimum could affect any patient needing surgery or a C-section at Rancho Springs. Therefore, the Hospital took the actions outlined below in sections C. and D. to protect patients needing surgery or C-section. — 11/05/09

C. Actions to improve maintenance and monitoring of humidity in the operating rooms (ORs) and C-section ORs at Rancho Springs:

* The CEO verbally advised the Chair of the Board of Governors on 10/28/09 that the operating rooms — 11/06/09, 11/16/09, 12/14/09 &

Event ID:E4O411 1/5/2010 4:29:18PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Dennis Knox | TITLE: CEO | (X6) DATE: 1.15.10

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Continued From page 1

CN - Charge Nurse
CS - Cesarean Section
HVAC - Heating, Ventilation, Air Conditioning
L&D - Labor and Delivery
OB - Obstetrics
ops - Operations
OR - Operating Room
RSMC - Rancho Springs Medical Center

A 014 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

T22 DIV5 CH1 ART8-70837 (a) General Safety and Maintenance

(a) The hospital shall be clean, sanitary and in good repair at all times Maintenance shall include provision and surveillance of services and procedures for the safety and well-being of patients, personnel and visitors

Based on observation, interview, and record review, the facility failed to provide maintenance that shall include provisions and surveillance of services and procedures for the safety and well being of patients, personnel, and visitors by failing to ensure the humidity in the CS OR at RSMC was within acceptable range prior to performing elective CSs on three

(ORs) at the Hospital were taken off-line due to humidity problems. The Board of Governors met three times, on 11/06/09, 11/16/09, and 12/14/09, to discuss the humidity issues at the Hospital. At each of those meetings, the CEO presented to the Board of Governors the findings identified during the November survey, and the actions the Hospital had taken to address the findings. Subsequently, the Board of Governors directed the CEO and senior leadership team to continue implementing process improvements for monitoring and acting on the issues identified, and to report progress to the Board of Governors at subsequent meetings. — ongoing

* The Chief Nursing Officer reviewed and revised the policy on monitoring temperature and humidity in the peri-operative areas as follows: — 11/05/09

--The circulating RN (rather than a technician) must check and log temperature and humidity in peri-operative areas before each case rather than just before the first case of the day to confirm temperature and humidity are in range.

--The reading must be done before bringing a patient into the OR.

--If a reading is out-of-range, staff must document the out-of-range reading

Event ID:E4O411 1/5/2010 4:29:18PM

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Continued From page 2

of three patients (Patients 1, 2, and 3), by performing the surgeries in a room where the humidity was too low. Patients 1 and 2 had elective CSs on October 26, 2009, when the recorded humidity in the room was 25%, and Patient 3 had an elective CS on October 28, 2009, when the recorded humidity in the room was 22%. This failed practice resulted in the potential for fire in the OR, and injury to mother and baby in the OR, as well as mothers and babies in the same suite as the CS OR (newborn nursery, two triage rooms, and three L&D rooms).

The event constituted an Immediate Jeopardy because the facility's failures caused, or were likely to cause serious injury or death to patients, pursuant to Health and Safety Code Section 1280.1(c).

Findings:

During a tour of the CS OR at RSMC on October 28, 2009, at 3 p.m., accompanied by the OB Manager, the humidity in the room was observed to be 20%. The manager stated no CSs were done that day, and they had cancelled a previously scheduled CS because the low humidity created a potential for fire in the room.

During an interview with OB Tech 1 on October 28, 2009, at 3:09 p.m., the tech stated she recorded a humidity of 25% in the room at 7 a.m., she reported it to her CN, and the CN

on a log.

--Staff must then notify Plant Operations of the out-of-range reading and initiate a work order.

--A Plant Operations staff member must immediately investigate and take appropriate action to bring the out-of-range level back into range.

--If any OR has a temperature or humidity reading that is not within compliance range, then that room is not to be used until Plant Operations staff has brought the temperature and/or humidity levels back within the appropriate ranges.

--Ongoing concerns are reported to the Plant Operations Manager, who forwards those concerns to Administrative Leadership.

* The Board of Governors approved the revisions to the humidity monitoring policy. — 11/16/09

* The Chief Nursing Officer developed a new Temperature/Humidity Log to use to document (1) all temperature and humidity readings in peri-operative areas prior to the start of each case, and, when temperature and/or humidity readings are not within the appropriate ranges, (2) that Plant Operations staff has brought any — 11/05/09

Event ID: E4O411 1/5/2010 4:29:18PM

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Continued From page 3

reported it to plant ops

A review of the humidity log for the CS OR at RSMC on October 29, 2009, indicated the low humidity readings started October 26, 2009 with entries as follows

a. October 26, 2009, 25% (plant ops notified); and,

b October 28, 2009, 22% (plant ops notified, plant ops director and administrator aware, scheduled case cancelled).

A review of the RSMC delivery room log on October 29, 2009, indicated two non emergent CSs were performed in the CS OR on October 26, 2009, and one non emergent CS was performed in the room on October 28, 2009.

*. The record for Patient 1 was reviewed on October 29 and November 3, 2009 Patient 1, a 28 year old female, was admitted to RSMC on October 26, 2009, for a repeat CS, when the recorded humidity in the CS room was 25%.

The labor and delivery summary indicated Patient 1 was not in labor on arrival

The labor notes indicated the patient presented to L&D at 11:20 a.m., "for scheduled CS," walked to the OR at 12 p.m., and the baby was delivered at 12 32 p.m

out-of-range readings back into range before any case proceeds in that OR.

* The Director of Medical Staff Services faxed an educational memorandum from the CEO regarding the changes to the policy to all physicians on the Medical Staff. — 11/05/09

* On 11/05/09, the Perioperative, Women's and Cardiovascular Services leadership team provided initial education on the revised policy and new form to all OR and L&D nursing staff. Education continued prior to each shift until 100% of appropriate staff were educated; no staff member began his or her shift without first being educated. Education of OR and L&D nursing staff included: (1) review of the revised policy, (2) review of the new Temperature/Humidity Log, and (3) demonstration on the use of temperature/humidity monitoring devices. — 11/05/09 & 11/19/09

* On 11/05/09, Plant Operations Managers provided initial education on the revised procedure to all members of the Plant Operations staff. Education continued prior to each shift until 100% of appropriate staff were educated; no staff member began his or her shift without first being educated. Education of Plant Operations staff included: (1) review of the new Temperature/Humidity Log and (2) — 11/05/09 & 11/08/09

Event ID:E40411 1/5/2010 4:29:18PM

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Continued From page 4

The anesthesia record indicated when the patient was taken into the OR, she was placed on oxygen.

The intraoperative nursing record indicated a bovie (an electrical cautery machine that uses heat to (1) make a surgical incision by burning and destroying tissue, or (2) close small bleeding blood vessels) was set up in the room and turned on.

The operative report, dictated by the surgeon October 28, 2009, indicated the initial incision was extended bilaterally (on both sides) using a bovie

2. The record for Patient 2 was reviewed on October 29 and November 3, 2009 Patient 2, a 31 year old female, was admitted to RSMC on October 26, 2009, for a repeat CS, when the recorded humidity in the CS room was 25%.

The labor and delivery summary indicated Patient 2 was not in labor on arrival

The labor notes indicated the patient presented at 3:30 p.m, for a, "scheduled CS," walked to the OR at 4:30 p m, and the baby was delivered at 5 03 p.m.

The anesthesia record indicated the patient was placed on oxygen in the OR

The intraoperative nursing record indicated a

expected response time and documentation requirements.

D. The Hospital implemented the following steps to monitor compliance with the corrective actions:

* The Chief Nursing Officer developed a report form for Department Directors to use to aggregate and report that temperature and humidity levels are checked and documented before each case, that Plant Operations staff is being notified if readings are out of range, and that Plant Operations staff is bringing the levels back into range and documenting that action before any case proceeds in that OR. — 11/05/09

* Department Directors use the new report form to report aggregated data from audits of 100% of the OR logs to assure compliance with the revised policy and procedure, and completeness of documentation. Daily audits began on 11/5/09 and continued until all staff were educated. Department Directors began aggregating data from the OR logs weekly. The Directors of Perioperative, Women's, and Cardiovascular Services are responsible for reporting compliance data on a monthly basis to the Quality Pillar, Patient Safety Council, Medical Executive Committee, and Board of Governors. The November compliance data was reported to the Board of — 11/05/09, 12/14/09 & ongoing

Event ID E40411 1/5/2010 4:29 18PM

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Continued From page 5

bovie was set up in the room and turned on.

The operative report, dictated by the surgeon on October 26, 2009, indicated the physician used fulguration to control bleeding (an electric spark that jumps from the bovie to the tissue, without the bovie actually touching the tissue, closing small blood vessels)

3. The record for Patient 3 was reviewed on October 29 and November 3, 2009 Patient 3, a 37 year old female, was admitted to RSMC on October 28, 2009, for a repeat CS, when the recorded humidity in the CS room was 22%.

The labor and delivery summary indicated Patient 3 was not in labor on arrival

The labor notes indicated the patient walked into the OR at 7:35 a.m (35 minutes after the staff obtained a humidity reading of 22%), and the baby was delivered at 8:01 a.m.

The anesthesia record indicated the patient was placed on oxygen in the OR.

The intraoperative nursing record indicated a bovie was set up in the room and turned on

The operative report, dictated by the surgeon on October 28, 2009, indicated the physician used fulguration to control bleeding (an electric spark that jumps from the bovie to the tissue, without the bovie actually touching the tissue,

Governors on 12/14/09. After three consecutive months of meeting 100% compliance, the Patient Safety Council will determine further auditing and reporting requirements.

The Hospital hereby also requests an informal conference with the district administrator/district manager to discuss the following additional information, which indicates that the Hospital was in compliance with this rule:

--The Hospital was monitoring humidity in the ORs daily before the first case of the day and notifying Plant Operations if humidity levels fell below the acceptable range. When extremely low atmospheric humidity led to difficulty maintaining the minimum humidity level in the ORs at RSMC, the Hospital self-reported the humidity issues to CDPH on 10/28/09 in order to request program flexibility so that the Hospital could resume surgeries at RSMC. In the meantime, the Hospital cancelled, rescheduled, or moved 24 surgeries to the IVMC ORs during that week.

--The citation mistakenly states that two C-sections were performed on 10/26/09 when the humidity was below 30%; Plant Operations staff had brought the humidity level back into proper range prior to the start of the first

Event ID E4O411 1/5/2010 4:29:18PM

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Continued From page 6

closing small blood vessels)

The pre scheduled CS records were reviewed on October 30, 2009, and indicated the following

a. Patient 1 was scheduled for an October 26, 2009, CS on September 22, 2009,

b. Patient 2 was scheduled for an October 26, 2009, CS on September 22, 2009; and,

c. Patient 3 was scheduled for an October 28, 2009, CS on October 6, 2009

The facility policy titled, "Temperature/Humidity Monitoring, Peri-Op," was reviewed on October 29, 2009 The policy indicated the following

a. The purpose of the policy was to monitor the temperature and humidity levels in the perioperative areas, as both were associated with principals of fire safety

b. The expected perioperative humidity range was 35-60%.

c. A staff member would record the readings on a log each day before the beginning of the first case, and.

d. A surgical case would not begin until the humidity in the OR was in the proper range

During an interview with OR RN 1on November

C-section. In accordance with the Temperature/Humidity Monitoring, Peri-Op Policy (Humidity Monitoring Policy) in effect at that time, nursing staff checked the humidity in the C-section OR at 8:30 a.m., noted that humidity was 25%, and notified Plant Operations. Before the start of Patient 1's C-section at noon, two maintenance engineers at the Hospital successfully brought the humidity in the C-section OR up to 36%, within the required humidity level range, and the two C-sections were able to proceed at 12:00 p.m. and 4:30 p.m. The Hospital has already provided evidence of these actions for further discussion at the informal conference.

--Although the citation is correct that one C-section was performed that week when the humidity level was 22%, this humidity level did not pose an immediate jeopardy. Recent scientific research indicates no increased risk of infection or fire with humidity levels above 20%. Although it appears that OB Tech I read the low humidity on October 28, she failed to document the low humidity level or notify anyone until after the performance of the C-section. At that time, the system subsequently corrected the problem and no patient was harmed as a result of the humidity level for the following reasons:

Event ID E4O411 1/5/2010 4 29 18PM

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Continued From page 7

4, 2009, at 1:40 p.m., the RN acknowledged low humidity created an increase risk for sparks and fire in the OR, and it was, "a given for a circulator (the RN in the room during a surgical case)," who should be continuously checking the humidity. The RN stated a fire risk assessment was done as part of the time out procedure before the surgical case started, but it did not include the humidity level.

The facility document titled, "Procedural Checklist With Fire Risk Assessment," was reviewed on November 4, 2009. The document included location of the surgical procedure, use of open flow oxygen, and use of a bovie as risks for fire. The document did not identify low humidity in the room as a risk.

According to the NFPA (National Fire Protection Act) 99, Standard for Health Care Facilities, Anesthetizing location are protected by maintaining relative humidity equal to or greater than 35%.

Patients 1, 2, and 3 had prescheduled, non emergent surgical procedures performed in the CS OR with low humidity and oxygen and a bovie in use, in violation of the facility policy, principles of fire safety, and AORN standards of practice.

A review of the RSMC floor plan indicated the OB CS OR was in the same suite as the newborn nursery, two triage rooms, and three L&D rooms. If a fire broke out in the CS OR, it

*When the Charge Nurse in Women's Services learned at 9:00 a.m. on October 28 that the humidity level in the C-section OR was 22%, she immediately contacted Plant Operations about the humidity level, and cancelled the remaining C-sections scheduled for that day.

*Since the survey, the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) has published its determination that scientific research finds no increased risk of infection or fire in ORs from humidity levels as low as 20%. ASHRAE concluded that the minimum humidity requirement is an outdated holdover from the era when flammable anesthetics were used in operating rooms, and has proposed reducing the minimum humidity level for short-term patient treatment stays to 20%. NFPA, which sets national fire safety standards, also plans to eliminate its 35% minimum humidity standard and follow the revised ASHRAE humidity standard.

--Finally, the risks to adjoining areas in the unlikely event a fire occurred in the C-section OR were remote. The C-section OR is contained within its own fire compartment, separated from those other areas by a one-hour fire-resistant smoke barrier wall and a one-hour fire-resistant occupancy separation wall.

Event ID:E4O411 1/5/2010 4:29:18PM

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Continued From page 8

could spread to those rooms.

On October 29, 2009, at 6:20 p.m., the CEO, COO, Director of Quality Outcomes, and Associate Administrator, were notified a serious and immediate threat to the health and safety of Patients 1, 2, and 3, as well as their babies, and the mothers and babies in the surrounding areas, was identified.

The facility's failure to ensure maintenance, including provisions and surveillance of services and procedures, to ensure the humidity in the OB CS OR was within appropriate and safe ranges, prior to performing three elective CSs, is a deficiency that has 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.

Event ID:E4O411 1/5/2010 4:29:18PM

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. 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