

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Printed: 05/26/2009
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050701	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 05/14/2009
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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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
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A 000 INITIAL COMMENTS

A 000

The following reflects the findings of the California Department of Public Health during a Complaint Validation survey (Complaint # CA00188084) authorized by the Centers for Medicare and Medicaid Services, Region IX, conducted May 11 through May 14, 2009. The Southwest Healthcare System is comprised of two hospitals under the same licensure (Inland Valley Medical Center and Rancho Springs Medical Center).

This Plan of Correction represents Southwest Healthcare System's allegation and commitment to compliance.

Representing the Department of Public Health:
Tina Buchanan, HFEN
Janne Powell, HFEN
Dongjoon Song, Pharm D, Pharmacy Consultant
Agnes Smith, RD, Nutrition Consultant
James Richards, MD, Medical Consultant
Jennifer Hoke, Infection Control Consultant

As a result of findings discovered during a state licensing visit, the CEO, COO, CNO, AA, and PI Director were notified Immediate Jeopardy was identified on May 11, 2009, at 5:40 p.m. The Immediate Jeopardy was identified due to the facility's failure to ensure:

A 000 Initial Comments
It is the policy of Southwest Healthcare System (SWHCS) to protect and ensure proper temperature controls in refrigerators and freezers containing patient food, to ensure the proper temperature controls in refrigerators containing breast milk, to ensure proper temperature controls in medication refrigerators, and to ensure proper ventilation in the Surgical and Women's Health Services areas on the RSM campus.

1. proper temperature controls in refrigerators and freezers (containing patient food) located in the kitchen and in each nursing unit at both campuses, resulting in the potential for foodborne illness in patients;
2. proper temperature controls in the refrigerators containing breast milk, located in the perinatal areas at both campuses, resulting in the potential for loss of nutritional benefit and immunological protection of the newborn;
3. proper temperature controls in the medication refrigerators located in the pharmacy and in each

09/11/09 1:31 PM
 DEPT OF HEALTH & HUMAN SERVICES
 IMMEDIATE JEOPARDY
 RSM

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

Dennis Knox CEO 7/29/09

A 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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A 000 Continued From page 1
nursing unit at both campuses, resulting in the potential for the medication to become ineffective; and,

A 000 Continued from page 1

4. proper ventilation in the perioperative areas (SPD, decontamination, and OB CS room) at the RSMC campus, resulting in mold growth in the decontamination room and the potential for infection in patients undergoing surgical procedures.

After implementation of an acceptable plan of correction, the CEO, GBM 1, COO, CNO, AA, MD, and PI Director were notified the Immediate Jeopardy was abated on May 14, 2009, at 5:05 p.m.

Abbreviations used in this document:

- > - Above
- AA - Assistant Administrator
- AORN - Association of peri-Operative Registered Nurses
- CCT - Critical Care Team
- CEO - Chief Executive Officer
- CGB - Chair of the Governing Board
- COO - Chief Operating Officer
- CS - Cesarean Section
- D5W - Dextrose 5% Water
- DI - Diabetes Insipidus
- DOP - Director of Pharmacy
- ED - Emergency Department
- EOC - Environment of Care Committee
- F - Fahrenheit
- FSW - Food Service Worker
- GB - Governing Board
- GBM - Governing Board Member
- HS - House Supervisor
- HVAC - Heating, Ventilation, Air Conditioning
- IC - Infection Control

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 RIVERSIDE COUNTY

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A 000 Continued From page 2
 ICD - Infection Control Director
 ICU - Intensive Care Unit
 IS - Information Systems/Services
 IV - Intravenous
 IVMC - Inland Valley Medical Center
 L&D - Labor and Delivery
 MD - Medical Doctor
 MEC - Medical Executive Committee
 mg - milligrams
 ml - milliliters
 NS - Normal Saline
 NSD - Nutrition Services Director
 NSM - Nutrition Services Manager
 OB - Obstetrics
 Ops - Operations
 OR - Operating Room
 PACU - Post Anesthesia/Recovery
 PI - Performance Improvement
 PIC - Performance Improvement Committee
 POC - Plan of Correction
 POD - Plant Operations Director
 RN - Registered Nurse
 RSMC - Rancho Springs Medical Center
 SNF - Skilled Nursing Facility
 SPD - Sterile Processing Department
 SO - Safety Officer
 SSM - Surgical Services Manager
 TAS - Temperature Assurance System

A 000 Continued from page 2

A 043 482.12 GOVERNING BODY

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

This Condition is not met as evidenced by:
Based on observation, interview, and record

A 043

Governing Body
It is the policy of Southwest Healthcare System to ensure that an effective governing body is legally responsible for the conduct of the hospital. The following actions were taken to assure an effective implementation of the Plan of Correction:

1. The CEO directed the voluntary discontinuation of the TAS and re-implemented the manual process for logging patient nourishment refrigerator/freezer temperatures, breast milk refrigerator temperatures, medication refrigerator temperatures, and perioperative temperature/humidity readings on a daily basis.

5/11/09	and	5/13/09
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A 043 Continued From page 3
review, the governing body was aware of the implementation of a new temperature and humidity monitoring system at both campuses, and failed to ensure implementation of the system included monitoring for accuracy and effectiveness and maintenance of patient safety, resulting in failure to recognize:

1. food refrigerator and freezer temperatures were reading out of range, resulting in the potential for foodborne illness (A726);
2. medication refrigerators were reading out of range, resulting in the potential for ineffective treatment of patients receiving refrigerated medications (A726);
3. temperature and humidity in the perioperative areas were reading out of range, resulting in growth of mold in the decontamination room and the potential for infection in patients undergoing surgical procedures (A726)(A940);
4. the DSM was not notified when food refrigerators and freezers were out of range, resulting in the inability to ensure food was safe for consumption (A726);
5. the DOP was not informed when medication refrigerators were out of range, resulting in the inability to ensure refrigerated medications were safe and effective when administered (A726);
6. staff was not trained in the use of the system, resulting in failure to respond to alerts and the potential for continued temperature and humidity values to be at unsafe levels (A726);
7. corrective action was not being performed when the system alerted with a temperature or

A 043 Continued from page 3

2. The Chief Nursing Officer (CNO) disseminated an email and memo that explained the change in process indicating that the BioMed Department would perform and document the daily refrigerator/freezer checks and take the necessary action to correct any out-of-range unit. The CNO directed the Surgical and Women's Services Directors to perform the daily logging of the perioperative area temperature and humidity readings. 5/13/09
3. The Board of Governors (BOG) met and the survey results were discussed including the immediate jeopardy that was identified due to the monitoring of temperature/humidity in the perioperative areas at Rancho Springs, and the monitoring of patient nourishment and medication refrigerators/freezers. Both were linked to the implementation of the TAS. Actions taken included the re-implementation of manual logging of temperature and humidity and the steps taken to address the ventilation system that supplies the periop area. The CoPs that were deemed non-compliant were discussed, the BOG expressed serious concerns over the findings, directed that an update be provided at each meeting as to the status of corrective actions taken. In addition the BOG is to be advised of any new system or program that may impact patient safety to ensure that appropriate planning for implementation and monitoring is complete. 5/18/09
4. The BOG met and received an update on the concerns identified in the CMS report with additional detail about the issues surrounding the TAS. The outcome of the meeting with CMS and representatives from UHS and SHA Consultants (6/19/09) including the negotiation of an agreement between the hospital and CMS. A six month monitoring period by an external Quality Monitor and a full validation survey to follow. The Board 6/24/09

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A 043 Continued From page 4
 humidity out of range, resulting in consistent out of range values and the potential for food, medications, and perioperative areas to be unsafe (A726);

8. contents of refrigerators had not been verified by the SO, resulting in some refrigerators with food being set with medication ranges (too hot) and some refrigerators with medications being set with food ranges (too cold) and the potential for unsafe food and medications (A726);

8. the ICD identified and reported high temperatures and humidity in the decontamination room at RSMC resulted in growth of mold on the wall, resulting in the potential for infection in patients undergoing surgical procedures (A726)(A940);

9. surgical instruments were being cleaned, sterilized, and stored in areas with temperature and humidity consistently higher than the acceptable range, resulting in the potential for infection in patients undergoing surgical procedures (A726)(A940);

10. no policies and procedures were developed to direct staff in how to use the system, resulting in inability to take corrective action if a value out of range was identified, and the potential for food, medications, and perioperative areas to be unsafe due to consistent out of range values (A726); and,

11. no PI indicators were being monitored to determine the accuracy, effectiveness, and safety of the newly implemented system, resulting in the inability to identify and correct the system failures (A726)(A263)

A 043 Continued from page 4
 stated they would provide the necessary resources to resolve these issues and expressed confidence that the hospital leaders would take the necessary actions.

5. The Board met to approve the elements of the hospital's CMS Plan of Correction and the policies associated with this plan including, Surveillance, Infection Control, Refrigerator/Freezer Temperature Checks, Stocking, Product Rotation, Cleaning and Defrosting, Temperature/Humidity, Periop, Control of Hospital Temperature, Work Order Requests, and Breast Milk: Collection, Storage and Handling. 7/28/09

Monitoring: To ensure an accurate and effective revised process, the BOG directed the following monitoring plan:

1. The Board of Governors is to receive a report including monitoring data at each regular meeting to verify that the hospital is taking appropriate actions to ensure that staff is following the revised hospital policies and procedures. Administration provides the Board an explanation for any variation and the steps taken to correct the issue. Upon achieving three consecutive months of 100% compliance in all areas, the Board will make a determination to what extent ongoing monitoring is to occur. 6/24/09

Person Responsible: CEO

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A 043	Continued From page 5 The cumulative effect of this systemic failure resulted in failure of the governing body to ensure care was provided throughout the organization in a safe and effective manner. Findings: The TAS system was implemented in September 2008 at both campuses to perform wireless monitoring of ambient temperatures in food, medication, breast milk, laboratory, radiology, and cardio-pulmonary refrigerators and freezers, as well as temperature and relative humidity in the perioperative areas. The system was designed to send computerized alerts to the SO, PO, and HS computers when temperature or humidity were outside of the criteria established by the organization. Once these alerts were sent, corrective action would take place to ensure patient safety. During the survey, the following was identified: 1. the system was not hooked up in the hospital's new building, so temperature and humidity were not being monitored; 2. corrective action was not being performed when the system alerted with a temperature or humidity out of range; 3. the HSs were not trained in the use of the system, but were expected to assist in ensuring corrective action was taken, so when alerts were sent to them, they did not know what corrective action to take; 4. food and medications were being stored at incorrect ranges;	A 043	Continued from page 5	

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5. the DOP was not notified when medication refrigerators were out of range, so refrigerated medications were not being checked to ensure they were safe and effective when administered;

6. the DSM was not notified when food refrigerators and freezers were out of range, so food was not being checked to ensure it was safe for consumption;

7. contents of refrigerators had not been verified by the SO, so some refrigerators with food were set with medication ranges (too hot) and some refrigerators with medications were set with food ranges (too cold);

8. the ICD identified and reported high temperatures and humidity in the decontamination room at RSMC went uncorrected which resulted in growth of mold on the wall;

9. surgical instruments were being cleaned, sterilized, and stored in areas with temperature and humidity consistently higher than the acceptable range; and,

10. no policies and procedures were developed to direct staff in how to use the system.

According to the "Performance Improvement Plan - 2008" (revised September 2008):

1. the governing board was responsible for establishing and maintaining the organization's PI program;

2. the governing board required staff to implement and report activities for identifying and evaluating opportunities to improve patient care

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A 043 Continued From page 7
and services;

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3. the governing board would assist in establishing PI priorities to ensure the needs of the community were met; and,

4. redesigned processes (the TAS was a redesigned temperature and humidity monitoring process) would be monitored.

During an interview with the SO on May 11, 2009, at 4:50 p.m., the SO stated he had not submitted reports regarding the success or failure of the temperature monitoring system. He further stated he had not yet checked each refrigerator on the nursing units to verify whether the unit contained food or medications. The SO stated he realized the acceptable temperature ranges for food and medication were different, and there was a potential danger to patients if food was stored at medication ranges (too hot) and medication was stored at food ranges (too cold), but he had not, "had time," to ensure the correct ranges were assigned to each unit.

During an interview with the PI Director on May 12, 2009 at 1:40 p.m. the Director confirmed the system went live in September 2008. The PI Director stated there was no data collected or analyzed during the validation phase to confirm the system accuracy. The PI Director stated the SO presented validation of the system using, "verbal data," and there was no written data provided. The PI Director stated there was no discussion or action in the PIC to recommend data collection to analyze the safety, reliability, and accuracy of the newly implemented system.

On May 12, 2009, at 2:30 p.m., the PI Director stated the SO presented an EOC PI plan to the

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A 043 Continued From page 8

GB on July 28, 2008. According to the GB minutes, the EOC Proposed PI Indicators included monitoring of the computer temperature system. The PI Director was asked to provide the data submitted to date. The PI Director stated she had not received any PI data since the implementation of the new system on September 9, 2008.

During an interview with the PI Director on May 14, 2009, at 10:50 a.m., the PI Director stated the PI program was structured so the EOC PI data was reported directly to MEC and then to the GB on an annual basis. She stated the EOC indicators did not get reported to the PI Committee.

On May 14, 2009, at 11:05 a.m., the PI Director stated it would be reasonable to expect data to be collected and analyzed to ensure the system was safe and effective.

A review of the GB minutes for September 15 and November 17, 2008, and January 19, 2009, showed there was no data presented to the GB that addressed the accuracy and effectiveness of the TAS system. There was no discussion or action in the minutes by the GB to request data be provided to the GB regarding the TAS system.

On May 14, 2009, at 1:10 p.m. the CGB and two physician GB members (GB1 and 2) were interviewed. The CGB stated she knew the TAS system had been implemented, but that she did not know much about it. GB 1 stated the GB had received, "reports," but none of them were regarding the accuracy or effectiveness of the TAS system. The CGB stated the GB received an EOC report annually, but they had not received any specific data regarding the implementation of

A 043

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A 043 Continued From page 9
the TAS system. The CGB further stated she had not been told of the temperature and humidity problems in the facility, "until today." The CGB stated if the problem was not brought to the attention of the GB, then, "the board presumes everything is okay." The CGB further confirmed there was no GB PI review of hospital departments and services unless problems were identified.

There was no monitoring or oversight of the implementation of this new process, and the governing body was not aware the system was failing to ensure a safe environment for their patients.

A 263 482.21 QAPI

The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

This Condition is not met as evidenced by: Based on observation, interview, and record review, the facility failed to maintain hospital wide PI by not including EOC information in the PI reports and discussions, and failed to implement quality indicators to assess the accuracy and

A 043 Continued from page 9

A 263 QA/PI

It is the policy of Southwest Healthcare System to ensure that an effective ongoing, hospital-wide, data driven quality assessment and performance improvement program is developed, implemented, and maintained. The following actions were taken to assure an effective implementation of the Plan of Correction:

1. The CEO directed the voluntary discontinuation of the TAS and re-implemented the manual process for logging patient nourishment refrigerator/freezer temperatures, breast milk refrigerator temperatures, medication refrigerator temperatures, and perioperative temperature/humidity readings on a daily basis.	5/11/09 and 5/13/09
2. The Chief Nursing Officer (CNO) disseminated an email and memo that explained the change in process indicating that the BioMed Department would perform and document the daily refrigerator/freezer checks and take the necessary action to correct any out-of-range unit. The CNO directed the Surgical and Women's Services Directors to perform the daily logging of the perioperative area temperature and humidity readings.	5/13/09

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effectiveness of the newly implemented temperature and ventilation monitoring process, resulting in failure to identify and correct as follows:

1. food refrigerator and freezer temperatures were reading out of range, resulting in the potential for foodborne illness (A726);
2. medication refrigerators that were reading out of range, resulting in the potential for ineffective treatment of patients receiving refrigerated medications (A726);
3. temperature and humidity in the perioperative areas that were reading out of range, resulting in growth of mold in the decontamination room and the potential for infection in patients undergoing surgical procedures (A726)(A940);
4. the DSM was not notified when food refrigerators and freezers were out of range, resulting in the inability to ensure food was safe for consumption (A726);
5. the DOP was not informed when medication refrigerators were out of range, resulting in the inability to ensure refrigerated medications were safe and effective when administered (A726);
6. staff was not trained in the use of the system, resulting in failure to respond to alerts and the potential for continued temperature and humidity values to be at unsafe levels (A726);
7. corrective action was not being performed when the system alerted with a temperature or humidity out of range, resulting in consistent out of range values and the potential for food, medications, and perioperative areas to be

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See additional details below in Tags A267 and A312 for further action taken, monitoring and person responsible.

CA DEPT OF
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PROCESSING & CERT.
ALPINE COUNTY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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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
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unsafe (A726);

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8. contents of refrigerators had not been verified by the SO, resulting in some refrigerators with food being set with medication ranges (too hot) and some refrigerators with medications being set with food ranges (too cold) and the potential for unsafe food and medications (A726);

8. the ICD identified and reported high temperatures and humidity in the decontamination room at RSMC resulting in growth of mold on the wall, resulting in the potential for infection in patients undergoing surgical procedures (A726)(A940);

9. surgical instruments were being cleaned, sterilized, and stored in areas with temperature and humidity consistently higher than the acceptable range, resulting in the potential for infection in patients undergoing surgical procedures (A726)(A940); and,

10. no policies and procedures were developed to direct staff on how to use the TAS system, resulting in the inability to take corrective action if a value out of range was identified, and the potential for food, medications, and perioperative areas to be unsafe due to consistent out of range values (A726).

The cumulative effect of this systemic failure resulted in failure to ensure care was provided in a safe and effective manner.

Findings:

The TAS system was implemented in September 2008 at both campuses to perform wireless monitoring of ambient temperatures in food,

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medication, breast milk, laboratory, radiology, and cardio-pulmonary refrigerators and freezers, as well as temperature and relative humidity in the perioperative areas. The system was designed to send computerized alerts to the SO, PO, and HS computers when temperatures or humidity were outside of the criteria established by the organization. Once these alerts were sent, corrective action would take place to ensure patient safety.

During the survey, the following was identified:

1. the system was not hooked up in the hospital's new building, so temperature and humidity were not being monitored;
2. corrective action was not being performed when the system alerted with a temperature or humidity out of range;
3. the HSs were not trained in the use of the system, but were expected to assist in ensuring corrective action was taken, so when alerts were sent to them, they did not know what corrective action to take;
4. food and medications were being stored at incorrect ranges;
5. the DOP was not notified when medication refrigerators were out of range, so refrigerated medications were not being checked to ensure they were safe and effective when administered;
6. the DSM was not notified when food refrigerators and freezers were out of range, so food was not being checked to ensure it was safe for consumption;

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A 263 Continued from page 13

7. contents of refrigerators had not been verified by the SO, so some refrigerators with food were set with medication ranges (too hot) and some refrigerators with medications were set with food ranges (too cold);

8. the ICD identified and reported high temperatures and humidity in the decontamination room at RSMC, that went uncorrected, resulting in growth of mold on the wall;

9. surgical instruments were being cleaned, sterilized, and stored in areas with temperatures and humidity consistently higher than the acceptable range; and,

10. no policies and procedures were developed to direct staff in how to use the system.

During an interview with the SO on May 11, 2009, at 4:50 p.m., the SO stated he had not submitted reports regarding the success or failure of the temperature monitoring system. He further stated he had not yet checked each refrigerator on the nursing units to verify whether the unit contained food or medications. The SO stated he realized the acceptable temperature ranges for food and medication were different, and there was a potential danger to patients if food was stored at medication ranges (too hot) and medication was stored at food ranges (too cold), but he had not, "had time," to ensure the correct ranges were assigned to each unit.

During an interview with the PI Director on May 12, 2009 at 1:40 p.m. the Director stated the system went live in September 2008. The PI Director stated there was no data collected or analyzed during the validation phase to confirm

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the system accuracy. The PI Director stated the SO presented validation of the system using "verbal data," and there was no written data provided. The PI Director stated there was no discussion or action in the PIC to recommend data collection to analyze the safety, reliability, and accuracy of the newly implemented system.

On May 12, 2009, at 2:30 p.m., the PI Director stated the SO presented an EOC PI plan to the GB on July 28, 2008. According to the GB minutes, the EOC Proposed PI Indicators included monitoring of the computer temperature system. The PI Director was asked to provide the data submitted to date. The PI Director stated she had not received any PI data since the implementation of the new system on September 9, 2008.

During an interview with the PI Director on May 14, 2009, at 10:50 a.m., the PI Director stated the PI program was structured so the EOC PI data was reported directly to MEC and then to the GB on an annual basis. She stated the EOC indicators did not get reported to the PI Committee.

On May 14, 2009, at 11:05 a.m., the PI Director stated it would be reasonable to expect data to be collected and analyzed to ensure the system was safe and effective.

According to the "Performance Improvement Plan - 2008" (revised September 2008):

1. the PI Department Director would aggregate, "maintain interdisciplinary collaboration and identify issues relating to operations, systems, and patient safety";

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2. redesigned processes (the TAS was a redesigned temperature and humidity monitoring process) would be monitored; and,

3. the PIC would review departmental PI reports presented by managers, and identify opportunities to improve processes with a focus on patient safety and quality of care.

The implementation of this new process was not monitored, and the facility was not aware the system was failing to ensure a safe environment for their patients.

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A 267 482.21(a)(2) QAPI QUALITY INDICATORS

The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations.

This Standard is not met as evidenced by:
Based on interview and record review, the facility failed to ensure the PI program included measurement, analysis, and tracking of quality indicators to assess the effectiveness of a newly implemented temperature and ventilation monitoring process by failing to monitor the accuracy and effectiveness of measuring:

1. temperature controls in refrigerators and freezers (containing patient food) located in the kitchen and in each nursing unit at both campuses, resulting in the potential for foodborne illness in patients due to temperatures being out of acceptable range;
2. temperature controls in the refrigerators containing breast milk, located in the perinatal areas at both campuses, resulting in the potential

A 267

QA/PI Quality Indicators
It is the policy of Southwest Healthcare System to measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations. The following actions were taken to assure an effective implementation of the Plan of Correction:

1. The CEO directed the voluntary discontinuation of the TAS and re-implemented the manual process for logging patient nourishment refrigerator/freezer temperatures, breast milk refrigerator temperatures, medication refrigerator temperatures, and perioperative temperature/humidity readings on a daily basis. 5/11/09
and
5/13/09
2. Established a manual system for daily temperature monitoring of patient refrigerators, patient freezers, medication refrigerators, and refrigerators housing breast milk were implemented with thermometers placed in each refrigerator/freezer. 5/11/09
3. The CNO and Administrative Director of Quality Outcomes (ADQO) met to identify following: 5/13/09
 - a. Range parameters for food/breast milk, medication refrigerators and for the perioperative temperature/humidity were

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for loss of nutritional benefit and immunological protection of the newborn due to the absence of a secondary thermometer so the nurses could verify the temperature;

3. temperature control in the medication refrigerators located in the pharmacy and in each nursing unit at both campuses, resulting in the potential for the medication to become ineffective due to temperatures being out of acceptable range; and,

4. ventilation in the perioperative areas (SPD, decontamination, and OB CS room) at the RSMC campus, resulting in mold growth in the decontamination room and the potential for infection in patients undergoing surgical procedures due to temperatures and humidities being out of range.

Findings:

The facility implemented a TAS system in September 2008. The TAS system was implemented to monitor ambient temperatures in food, medication, breast milk, laboratory, radiology, and cardio-pulmonary refrigerators and freezers throughout the two hospital campuses. In addition, the TAS would monitor room temperature and relative humidity in the surgical areas of the hospital. The system was designed to send computerized alerts to the SO, Plant Ops, and HS computers when temperatures or humidities were outside of the established criteria in the system. Once these alerts were sent, corrective action should take place to ensure patient safety.

During the survey, the following was identified:

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verified by each appropriate Director based upon industry/regulatory requirements. The ranges were printed on the log forms.

b. Directors to provide information to their staff regarding the revised process and how to notify the appropriate department director/manager for an out-of-range reading.

c. Indicators for the revised monitoring process were defined as the number of days in range, and that action is taken for each out-of-range reading.

4. Based upon the initial reports reviewed and discussed by the Quality Monitor, CNO and ADQO, the PI indicators were revised. Data from the July logs will be reviewed for the following:

d. Daily checks are to be done and documented – Goal: 100% Compliance.

e. Action is taken for every out-of-range reading and documented appropriately – Goal: 100% Compliance.

Monitoring: In addition, SWHCS also established the following monitoring processes to ensure that the corrections are permanent:

1. The Board of Governors is to receive a report at each regular meeting to verify that the hospital is taking appropriate actions to ensure that staff is following the revised hospital policies and procedures. Administration provides the Board an explanation for any variation and the steps taken to correct the issue. Upon achieving three consecutive months of 100% compliance in all areas, the Board will make a determination to what extent ongoing monitoring is to occur.

2. All refrigerator/freezer temperature logs and the perioperative temperature and humidity logs will be submitted on a monthly basis to each Director's Senior Team member. (Dietary – Associate Administrator. Pharmacy, Surgery and Women's Service –

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1. the system was not hooked up in the hospital's new building;
2. the HSs did not know how the system worked;
3. corrective action was not being performed when the system alerted with a temperature or humidity out of range;
- 4). food and medications were being stored at incorrect ranges; and
5. the DOP was not notified when medication refrigerators were out of range.

On May 12, 2009 at 1:40 p.m. the PI Director stated the system went live in September 2008.

According to the minutes of the, "Operational PI Committee," dated September 9, 2008, the validation of the system prior to implementation took longer than expected. The PI Director stated there was no data collected or analyzed during the validation phase which confirmed the system accuracy. The PI Director stated the presentation of the system validation included, "verbal data," and there was no specific data presented. The PI Director stated there was no discussion or action in the PIC to recommend data collection to analyze the safety, reliability, and accuracy of the newly implemented TAS system.

On May 12, 2009 at 2:30 p.m. the PI Director stated the SO presented an EOC PI plan to the GB on July 28, 2008. According to the GB minutes, the EOC Proposed PI Indicators included monitoring of the computer temperature system. The PI Director was asked to provide the data submitted to date. The PI Director stated she had not received PI data since the

A 267 Continued from page 16

Chief Nursing Officer). The Administrator will review the log to ensure that daily logging has been done and if there is an out-of-range reading, the action taken to return the unit/area to the proper range is documented. The data will be aggregated and reported to the PI/RM Committee for analysis, issue identification and action planning as appropriate. The information is to forward to the BOG at each of their regular meeting. PI Indicators:
Daily checks are to be done and documented – Goal: 100% Compliance.
Action is taken for every out-of-range reading and documented appropriately – Goal: 100% Compliance.

3. Each monitoring department has included the temperature and humidity process in their PI activities, with indicators identified. **7/1/09**

4. Reports on the monitoring of this plan of correction will also forward to the Environment of Care Committee. The P&T Committee will receive the report regarding patient nourishment and medication refrigerator/freezers. The Infection Control Committee will receive the report regarding the perioperative areas. **7/1/09**

5. Infection Control rounds in the perioperative area include a check of the perioperative temperature and humidity logs. **7/14/09**

Persons Responsible:
Daily Monitoring: Dietary, Pharmacy, Surgical & Women's Services Directors
Documentation of Actions if Out-of-Range Reading: Plant Operations Manager
Oversight and Reporting: Associate Administrator and Chief Nursing Officer

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implementation of the new system on September 9, 2008.

During an interview with the PI Director on May 14, 2009, at 10:50 a.m., the PI Director stated the PI program was structured so the EOC PI data was reported directly to MEC and then the GB on an annual basis. She stated the EOC information did not get reported to the Operational PI Committee.

On May 14, 2009 at 11:05 a.m., the PI Director stated it would be reasonable to expect data to be collected and analyzed to ensure the system was safe and effective.

According to the "Performance Improvement Plan - 2008" (revised September 2008) the PI Department Director would aggregate and analyze improvement findings and, "maintain interdisciplinary collaboration and identify issues relating to operations, systems, and patient safety."

Further review of the PI plan indicated redesigned processes (the TAS was a redesigned temperature and humidity monitoring process) would be monitored. There was no monitoring of the accuracy and effectiveness of the TAS system.

A 312 482.21(e)(2) EXECUTIVE RESPONSIBILITIES

That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care ... and that all improvement actions are evaluated.

This Standard is not met as evidenced by:
Based on observation, interview, and record review, the hospital's GB failed to monitor the

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QA/PI Executive Responsibilities
It is the policy of Southwest Healthcare System to ensure that the BOG is responsible for hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care, and that the actions are evaluated. The following actions were taken to assure an effective implementation of the Plan of Correction:

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effectiveness of a newly implemented temperature monitoring system. (Cross refer A726 and A267)

Findings:

The TAS monitors ambient temperatures in food, medication, breast milk, laboratory, radiology and cardio-pulmonary refrigerators and freezers throughout the two hospital campuses. In addition, the TAS monitors relative humidity in the surgical areas of the hospital. The system was designed to send computerized alerts to the SO, Plant Ops and the nursing HS computers when temperatures or humidity were outside of the established criteria in the system. Once these alerts were sent, corrective action should take place to ensure patient safety. During the survey, systemic problems had been identified relating to the system implementation, training, accuracy and reliability (Cross refer A726).

On May 12, 2009, at 1:40 p.m., the PI Director stated the TAS system went live in September 2008. The PI Director stated there was no discussion or action in the PIC to recommend data collection to analyze the safety and efficacy of the newly implemented system to assess the system safety, reliability and accuracy.

On May 12, 2009, at 2:30 p.m., the PI Director stated the SO had presented the EOC PI plan to the GB on July 28, 2008. According to the GB minutes, the EOC Proposed PI indicators included monitoring of the computer temperature system. The PI Director was asked to provide the data submitted to date. The PI Director stated she had not received PI data since the implementation of the new system on September 9, 2008.

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1. The CEO directed the voluntary discontinuation of the TAS and re-implemented the manual process for logging patient nourishment refrigerator/freezer temperatures, breast milk refrigerator temperatures, medication refrigerator temperatures, and perioperative temperature/humidity readings on a daily basis. 5/11/09 and 5/13/09
2. Established a manual system for daily temperature monitoring of patient refrigerators, patient freezers, medication refrigerators, and refrigerators housing breast milk were implemented with thermometers placed in each refrigerator/freezer. 5/11/09
3. The Board of Governors (BOG) met and the survey results were discussed including the immediate jeopardy that was identified due to the monitoring of temperature/humidity in the perioperative areas at Rancho Springs, and the monitoring of patient nourishment and medication refrigerators/freezers. Both were linked to the implementation of the TAS. Actions taken included the re-implementation of manual logging of temperature and humidity and the steps taken to address the ventilation system that supplies the periop area. The CoPs that were deemed non-compliant were discussed, the BOG expressed serious concerns over the findings, directed that an update be provided at each meeting as to the status of corrective actions taken. In addition the BOG is to be advised of any new system or program that may impact patient safety to ensure that appropriate planning for implementation and monitoring is complete. 5/18/09
4. The BOG met and received an update on the concerns identified in the CMS report with additional detail about the issues surrounding the TAS. The outcome of the meeting with CMS and representatives from UHS and SHA Consultants (6/19/09) including the negotiation of an agreement between the hospital and CMS. A six month monitoring period by an external Quality Monitor and a full validation survey to follow. The BOG stated they would provide the 6/24/09

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On May 14, 2009, at 11:05 a.m., the PI Director stated it would be reasonable to expect data to be collected and analyzed to ensure the system was safe and effective. Unless a problem had been identified, there was no on-going PI reporting to the GB to review hospital departments and services to ensure patients are receiving safe and effective care (Cross refer A267).

A review of the GB minutes for September 15, 2008, November 17, 2008, and January 19, 2009 showed there was no data presented to the GB that addressed the safety and efficacy of the TAS system. There was no discussion or action in the minutes by the GB to request data be provided to the GB regarding the TAS system.

According to the facility, "Performance Improvement Plan - 2008" (revised 9/2008), the GB is responsible for establishing and maintaining the organization's PI plan. The PI Plan also documented the GB supports the systemic organization wide approach to design, measure, assess and improve organization performance. Among the organizational initiatives, the commitment to patient safety was to be preserved. In addition, the GB required the organizational staff to implement and report activities for identifying and evaluating opportunities to improve care and services throughout the organization.

On May 14, 2009, at 1:10 p.m. the CGB and two physician GB members (GB1 and 2) were interviewed. The CGB stated the TAS had been implemented but that she did not know much about it. GB 1 stated that they had received "reports." The CGB stated the GB received an EOC report annually, but that they had not

A 312 Continued from page 20

necessary resources to resolve these issues and expressed confidence that the hospital leaders would take the necessary actions.

5. The Board met to approve the elements of the hospital's CMS Plan of Correction which includes the QI/PI process and the indicators for monitoring compliance with the manual logging procedure. 7/28/09

Monitoring: To ensure an accurate and effective revised process, the BOG directed the following monitoring plan:

1. All refrigerator/freezer temperature logs and the perioperative temperature and humidity logs will be submitted on a monthly basis to each Director's Senior Team member. (Dietary - Associate Administrator, Pharmacy, Surgery and Women's Service - Chief Nursing Officer). The Administrator will review the log to ensure that daily logging has been done and that if there is an out-of-range reading, that the log notes the action taken to return the unit/area to the proper range. The data will be aggregated and reported to the PI/RM Committee for analysis, issue identification and action planning as appropriate. 6/1/09

PI Indicators:
Daily checks are to be done and documented - Goal: 100% Compliance.
Action is taken for every out-of-range reading and documented appropriately - Goal: 100% Compliance.

2. The Board of Governors is to receive a report including monitoring data at each regular meeting to verify that the hospital is taking appropriate actions to ensure that staff is following the revised hospital policies and procedures. Administration provides the Board an explanation for any variation and the steps taken to correct the issue. Upon achieving three consecutive months of 100% compliance in all areas, the Board will make a determination to what extent ongoing monitoring is to occur. 6/24/09

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received any specific data regarding the implementation. The CGB further stated that she had not been told of the temperature and humidity problems in the facility until today. The CGB stated if the problem is not brought to the attention of the GB, then, "everything is okay." The CGB further stated that there was no GB PI review of hospital departments and services unless problems are identified.

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Person Responsible: CEO

A 700 482.41 PHYSICAL ENVIRONMENT
The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

This Condition is not met as evidenced by:
Based on observation, interview, and record review, the facility failed to ensure proper ventilation and temperature controls in pharmaceutical, food preparation, and patient care areas on both hospital campuses by failing to ensure:

1. proper temperature controls in refrigerators and freezers (containing patient food) located in the kitchen and in each nursing unit at both campuses, resulting in the potential for foodborne illness in patients (A726);

2. proper temperature controls in the refrigerators containing breast milk, located in the perinatal areas at both campuses, resulting in the potential for loss of nutritional benefit and immunological protection of the newborn (A726);

3. proper temperature controls in the medication refrigerators located in the pharmacy and in each nursing unit at both campuses, resulting in the

A 700 Physical Environment
Proper Temperature Controls: (1) Patient Food Refrigerators/Freezers, (2) Breast Milk Refrigerator and (3) Medication Refrigerators. The following actions were taken to assure an effective implementation of the Plan of Correction:
Upon notification by the survey team of concerns regarding the appropriate monitoring of the food, breast milk and medication refrigerators, the CEO voluntarily directed that the TAS be immediately discontinued and that the temperatures be monitored manually. Appropriate NSF thermometers were purchased and placed in each unit. Logs which list the appropriate range for each type of unit were provided. The BioMed staff members were assigned the responsibility to monitor all refrigerators on a daily basis, to record the temperature, to take action if the unit was not within the proper range for the contents, and to document the action taken if a reading was noted to be out-of-range.
Please refer to Tag 726 for additional details of the plan of correction, including action taken, monitoring and person responsible. 05/11/2009
(4) Proper Ventilation in the Perioperative Areas
Upon notification by the survey team of concerns regarding the appropriate monitoring of perioperative temperature and humidity levels, the CEO voluntarily directed that the TAS be immediately discontinued and that the temperatures be monitored manually. The hospital purchased new thermometer /

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A 700 Continued From page 22
potential for the medication to become ineffective (A726); and,

4. proper ventilation in the perioperative areas (SPD, decontamination, and OB CS room) at the RSMC campus, resulting in mold growth in the decontamination room and the potential for infection in patients undergoing surgical procedures (A726)(A940).

The cumulative effect of this systemic problem resulted in failure to ensure the provision of care in a safe environment.

A 726 482.41(c)(4) VENTILATION, LIGHT, TEMPERATURE CONTROLS

There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

This Standard is not met as evidenced by: Based on observation, interview and record review, the facility failed to ensure proper ventilation and temperature controls in pharmaceutical, food preparation, and patient care areas on both hospital campuses by failing to ensure:

- proper temperature controls in refrigerators and freezers (containing patient food) located in the kitchen and in each nursing unit at both campuses, resulting in the potential for foodborne illness in patients;
- proper temperature controls in the refrigerators containing breast milk, located in the perinatal areas at both campuses, resulting in the potential for loss of nutritional benefit and immunological protection of the newborn;

A 700 Continued from page 22

hygrometers and installed them in each perioperative area, the four (4) operating rooms, the SPD area and the SPD/Decontamination area. The surgical staff members were assigned the responsibility to monitor the temperature and humidity readings in the perioperative areas, to record the readings, to take action if the reading was not within the proper range and to document the action taken if a reading was noted to be out-of-range. Please refer to Tag 726 for additional details of the plan of correction including action taken, monitoring and person responsible.

A 726 Ventilation, Light, Temperature Controls
Corrective Action:

Proper Temperature Controls: Patient Food Refrigerators/Freezers, Breast Milk Refrigerator and Medication Refrigerators

1. Immediate Action: The hospital took the following actions to ensure the proper temperatures of the patient nourishment and medication refrigerators/freezers.

Effective 05/11/2009, the hospital reinstated a manual log for all refrigerators/freezers that are used for patient nutrition and medication. Both the patient nourishment and medication refrigerators/freezers will be manually checked and temperatures logged today and on a daily basis.

Medication Refrigerator - RS PCU Nurses Station

A. The medications stored in that refrigerator were removed by the Pharmacist and appropriately discarded in pharmaceutical waste containers.

B. Plant Operations was contacted to assess the refrigerator, the setting was adjusted to bring the unit into the proper range. The adjustments were completed at 3:30pm.

C. At 7:00pm, the unit's temperature was manually checked and found to be in the acceptable range (39°F)

D. The PCU Medication refrigerator was

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3. proper temperature controls in the medication refrigerators located in the pharmacy and in each nursing unit at both campuses, resulting in the potential for the medication to become ineffective; and,

4. proper ventilation in the perioperative areas (SPD, decontamination, and OB CS room) at the RSMC campus, resulting in mold growth in the decontamination room and the potential for infection in patients undergoing surgical procedures.

Findings:

On May 11, 2009, at 10:30 a.m., during a tour of the L & D unit in the new hospital building, a yellow box measuring approximately four by two inches was observed in the patient nourishment freezer.

On May 11, 2009, at 10:45 a.m., the RSMC POD stated the unit was a wireless system, known as TAS, that monitored the temperature in the refrigerator/freezers and would alert if the temperatures went out of the established temperature ranges set by the facility. There was no other temperature measuring device located in the refrigerator/freezer. The POD further stated the temperature monitoring was done using a computer screen located in the basement of the Plant Operations/SO area.

The TAS was removed from the freezer and allowed to increase to room temperature. On May 11, 2009, at 11:05 a.m., the POD received a cell phone call. The POD stated the call was from the SO Department indicating that the L & D new building unit was alerting because it had increased in temperature outside of the safety

A 726 Continued from page 23

restocked by the Pharmacy.

All Medication Refrigerators

A. A designated staff member will physically round daily on all medication refrigerators to ensure that the unit is functioning in the proper range (36°F - 46°F).

B. During the regular monitoring, if the unit is out-of-range, the staff member will contact:

- i. Plant Operations to assess the functioning of the unit.
- ii. Actions taken by the Plant Operations staff will be documented on the log.
- iii. If the unit requires more than a minor adjustment, the Plant Operations staff member will contact the Pharmacist.

C. The Pharmacist is responsible to assess the contents of the refrigerator and will then determine the appropriate course of action. This may include transferring the drugs to storage in another area. If there is any concern regarding the quality/integrity of the medication, the Pharmacist will discard the medication.

Food Refrigerators

A. A designated staff member will physically round daily on all patient nourishment refrigerators/freezers to ensure that the unit is functioning in the proper range.
Refrigerators: 34°F - 40°F Freezer Range: 0°F or less

B. The staff member will also use a food thermometer to validate that the food itself is in the proper range as noted above. If the food temperature is noted to be out-of-range, it will be discarded.

C. During the regular monitoring, if the unit is out-of-range, the staff member will contact:

- a. Plant Operations to assess the function of the unit.
- b. Actions taken by the Plant Operations staff will be documented on the log.
- c. If the unit requires more than a minor adjustment, the Plant Operations staff

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parameters set in the system.

On May 11, 2009, at 11:20 a.m., the monitoring computer in the SO office was observed. The SO was asked to display and verify the L & D TAS information in the computer. The SO stated the system monitored ambient temperatures in food, medication, breast milk, laboratory, radiology, and cardio-pulmonary refrigerators and freezers throughout the two hospital campuses. The SO further stated the system was designed to send computerized alerts to the SO, Plant Ops, and HS computers when the temperatures were outside of the established criteria in the system. Once these alerts were sent, corrective action should take place to ensure patient safety. The SO stated the system went, "live," last year (2008). The SO confirmed there was no specific policy and procedure created to provide staff direction regarding alerts, communication, corrective actions, documentation and other operational features of the system.

An e-mail dated September 9, 2008, sent by the SO, showed managers were made aware that, "individual unit manual logging of food, medication and laboratory refrigerators/freezers is no longer required."

Further review of the alert computer screen showed the patient food temperature criteria for nursing unit food freezers was -20° to 32° F and for food refrigerators as 35.6° to 46.4° F. Further review of the criteria showed the temperature criteria in the dietary department freezers as -16.6° to 1.4° F and for the dietary department refrigerators as 33° to 40° F.

On May 11, 2009, at 11:30 a.m., the SO stated the food temperature ranges were inconsistent.

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member will contact the Dietary Director/Manager.

D. The Dietary Director or Manager is responsible to assess the contents of the refrigerator and will then determine the appropriate course of action. This may include transferring the food to storage in another area. If there is any concern regarding the quality/integrity

2. The CNO sent a memo to the hospital leadership explaining that the BioMed Department would check the patient food refrigerators/freezers, the breast milk refrigerator and the medication refrigerators. The appropriate range for each type of product in the unit was verified by the appropriate Director, based upon regulatory requirements.
Food Refrigerator Temperature Range: 34°F – 40°F
Food Freezer Temperature: ≤ 0°F
Breast Milk Refrigerator: 35°F – 39°F
Medication Refrigerator: 36°F – 46°F
The Dietary Department had been monitoring the refrigerator/freezer units physically located in the Dietary Department and did not rely on the TAS; the dietary staff continued this practice by logging the temperatures on a daily basis.

3. BioMed staff members were instructed by the COO to note the unit's temperature on the log. If the reading was out-of-range, the BioMed staff member was to take appropriate action (such as adjust the temperature) to return the unit to the proper range and to document the action taken on the log. If the unit could not be brought into range, the appropriate Director or designee will be notified.

4. The Director of Pharmacy reviewed and revised the pharmacy refrigerator monitoring policy. The policy was approved by the P&T Committee and the Policy & Procedure

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The SO stated, when the criteria was initially set-up in the computer, he used the individual departmental temperature monitoring policies and procedures. The SO further stated he had not consulted with the individual department managers regarding the standards required in their areas.

After three reviews of the system, "current status," computer screen, the SO was unable to verify the new building L&D unit was working and connected to the alert computer system, even though the system had alerted the POD.

On May 11, 2009, at 11:40 a.m., the SO printed from the hospital computer policies and procedures index, the dietary policy he had used to set the criteria for food in the TAS.

The policy titled, "Refrigerator/Freezer Temperature Checks, Stocking, Product Rotation, Cleaning & Defrosting," (reviewed May 2003) showed all readily perishable food or beverages, "capable of supporting rapid and progressive growth of microorganisms which can cause food infections or food intoxication shall be maintained at temperatures of 45° F or lower and frozen food shall be stored at 0°F or below." In addition, the policies showed a reliable thermometer shall be used for each refrigerator used for perishable food.

A review of the policy and procedure titled, "Temperature Recording, Dietary Refrigerator/Freezer Inside and Outside Units," (issued February 2008) showed all units used for food storage within the facility were to maintain safe food temperatures below 41° F. The policy further showed if food integrity and safety could not be determined over time, the food would be discarded.

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Committee.

5. The COO directed that the daily monitoring of the refrigerator/freezer temperatures would revert back to the departments that have primary responsibility and accountability for the contents of the unit.

Patient Nourishment Refrigerators/Freezers – Dietary Services
Breast Milk Refrigerators – Women's Services
Patient Medication Refrigerators – Pharmacy
6. Dietary, Women's Services and Pharmacy Directors directed their staff to resume their previous roles of monitoring unit temperatures and to notify Plant Operations if a unit was noted to be out-of-range. The Manager of Plant Operations reminded the engineering staff of their responsibility to document the actions taken to return the unit to the proper range on the log. If the unit requires more than a minor adjustment and can not be promptly returned to the proper range, the Plant Operations staff member is to notify 1) the Director of Nutritional Services (or designee) for nourishment refrigerators/freezers, and 2) the Pharmacy Director (or designee) for medication refrigerators. The Director will assess the situation and take appropriate action to ensure the integrity of the unit contents.

7. The Director and Manager of Nutritional Services reviewed and revised the policy, Refrigerator/Freezer Temperature Checks, Stocking, Product Rotation, Cleaning and Defrosting to give greater clarity to the process. The policy was approved by the Board of Governors.

8. The Director of Women's Services reviewed and revised the policy, Breast Milk: Collection, Storage and Handling to include the process for monitoring the breast milk refrigerator. Responsibilities include the daily logging of the unit's temperature and the steps to take if the unit is noted to be out-of-range. The policy was approved by the Board of Governors.

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On May 11, 2009, at 11:45 a.m., the SO was unable to state why the frozen food alert temperature was entered as 32° F when the policy showed frozen food shall be stored at 0° F or below.

On May 11, 2009, at 1:30 p.m., the NSD and NSM concurrently stated that the temperature standards for a food freezer should be kept at 0° to -10° F and for a food refrigerator should be between 38° to 40° F.

On May 11, 2009, further review of the, "current status," screen showed the main dietary freezer was 69.2° F. A review of the TAS graph showed from March 23, 2009 to April 7, 2009, the freezer temperature was well above the 1.4°F temperature maximum and was running approximately between 65° and 75° F. The TAS graph dated from April 11 to May 11, 2009 showed there was no recorded data.

On May 11, 2009, at 11:50 a.m., the SO was asked why the dietary main freezer was registering high and why there was no data for the last 30 days. The SO was unable to state what problem the unit was having or what specific corrective action had taken place.

On May 11, 2009, at 1:30 p.m., the dietary walk-in freezer was found to be operational and registered as -10° F. At that time, the NSD and NSM concurrently stated the temperature standards for a food freezer were -10° to 0° F.

On May 11, 2009, at 6:45 p.m., in a concurrent interview, the NSD and NSM stated they were aware of the TAS monitoring system. They stated the dietary department was also using a

9. The Associate Administrator and the Plant Operations Manager reviewed and revised the policy, Work Order Requests to include the information regarding the hospital's on-line work order request process. The policy was approved by the Board of Governors. 7/28/09

Corrective Action:
Proper Ventilation for the Perioperative Areas 5/13/09
1. Immediate Action: The hospital took the following actions.

Effective 05/13/2009, the hospital reinstated a manual log for temperature and humidity levels in operating rooms, SPD and the decontamination room at Rancho Springs Medical Center.

A. The hospital purchased six (6) new temperature/humidity monitors for the:
i. Four operating rooms (three in the main OR and one in the OB area)

ii. SPD area
iii. Decontamination room.

B. Daily, the Charge Nurse in the designated area will record the room temperature and humidity level on the log. On 05/13/09, the Chief Nursing Officer educated the Surgery and OB Nurse Directors regarding this process. The Surgery and Women's Directors/Managers are responsible for assuring that the Charge Nurse completes the daily documentation of room temperature and humidity.

i. The acceptable range for room humidity is 30% to 60%.

ii. The acceptable range for room temperature are as follows:

- Operating Room and SPD 68°F - 73°F

- Decontamination Area 60°F - 65°F

C. If any reading is out-of-range, the Charge Nurse will contact Plant Operations to assess the situation.

D. The Plant Operations engineer will take necessary action to correct the problem.

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continuous disk method to monitor the temperatures in the departmental refrigerators and freezers. A review of the disc monitoring system printouts showed that the freezer was working appropriately during the entire time from March 23 to May 11, 2009, despite the TAS data that showed the same freezer had been running between 65° and 75° F.

The NSD and NSM further stated they had not been notified about the main dietary freezer or any other food refrigerator/freezer being out of range during this time. The NSD and NSM stated if they had been notified via alerts about the refrigerators and freezers anywhere in the hospital, they would immediately monitor the internal temperatures of the actual food in the unit to ensure that it stayed within safe limits. The two also stated they did not have immediate access to the monitoring data as needed.

During an interview with HS1 on May 11, 2009, at 1:20 p.m., the HS stated she received alerts from the TAS when refrigerators/freezers were not within the acceptable ranges. The HS stated the alerts were transmitted to her computer; however the system, "went down," earlier that morning, and she was unable to view any alerts that may have been sent. The HS stated there were no downtime procedures for when the system was not functioning.

On May 11, 2009, further review of the, "current status," computer screen showed the breast milk refrigerator criterion in the OB area was 35.6° to 46.4° F.

A review of the facility policy and procedure titled, "Breast Milk: Collection, Storage & Handling," (revised December 2008) showed refrigerated

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i. Actions taken by the Plant Operations staff will be documented on the log.
ii. Additional documentation will be maintained by the Plant Operations Department as necessary.

E. As the Charge Nurse performs the daily checks, if there are two consecutive days in which the temperature and/or humidity exceed the maximum threshold, in addition to contacting Plant Operations, the Charge Nurse will notify the Infection Control Director. The Infection Control Director will initiate appropriate tracking of surgical patients.

Infection Control

A. The operating rooms are terminally cleaned on a daily basis. Previously, the SPD and decontamination rooms were terminally cleaned a weekly basis, however on 05/07/09, based upon the recommendation of the Infection Control Director, the Chief Operating Officer directed that terminal cleaning of SPD and the decontamination room be done on a daily basis.

B. Within the next 24-hours, the Infection Control Director will round with the EVS Manager in all operating rooms and the SPD and decontamination rooms to visually inspect them for cleanliness. Should any concern be identified, immediate action will be taken as directed by the Infection Control Director. If necessary, the use of the room will be suspended until cleared by Infection Control.

C. Upon notification by the Charge Nurse of an operating room, SPD or decontamination room exceeding the maximum threshold of temperature and/or humidity, the Infection Control Director will initiate targeted surveillance of surgical cases.

2. The CNO assigned the responsibility for daily monitoring of perioperative temperature and humidity to the Surgical Services and Women's Services Directors. The Directors instructed their staff to resume their previous role of monitoring the perioperative area 5/13/09

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breast milk should be stored at 39° F for no longer than 24 hours. The policy further showed safe handling and storage of breast milk would optimize nutritional benefits and ensure immunological protection.

The TAS graph, displaying 30 days of temperature monitoring for the PCU medication refrigerator at IVMC, was reviewed on May 11, 2009. The graph indicated the average temperature in the refrigerator was 60° F, above the maximum temperature criteria established by the facility (46° F).

During an interview with the SO on May 11, 2009, at 1:10 p.m., the SO stated he was not aware of the refrigerator being out of range for a month, he did not know why it was out of range, he did not know if any corrective action had been taken, and he did not have any alerts regarding this refrigerator.

The TAS graph, displaying 30 days of temperature monitoring for the PCU medication refrigerator at RSMC, was reviewed on May 11, 2009. The graph indicated the average temperature in the refrigerator was 32° F, below the minimum temperature criteria established by the facility (36° F). An alert was observed regarding this refrigerator. The alert indicated the refrigerator was, "consistently below the minimum range."

During an interview with the SO on May 11, 2009, at 1:10 p.m., the SO stated he was not aware of the refrigerator being out of range for a month, he did not know why it was out of range, and he did not know if any corrective action had been taken.

The medication refrigerator in the PCU at RSMC

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temperature/humidity levels and to notify Plant Operations if a reading was noted to be out-of-range. The Manager of Plant Operations reminded the engineering staff of their responsibility to respond immediately and document the actions taken to return the area to the proper range on the log. The appropriate Director is to be notified by Plant Operations if the area requires more than a minor adjustment to allow the Director to assess the situation and take the necessary action to ensure patient safety.

3. Purchased and installed new digital thermometers/hygrometers in the four operating rooms, SPD and the SPD/Decontamination areas at Rancho Springs. 5/13/09

4. After replacing the temperature and humidity monitors in the Rancho Springs peri-operative area, it was noted this morning that the temperature and humidity in the decontamination and SPD rooms was out-of-range. Plant Operations was notified and despite their efforts, the decontamination room in particular could not be brought into range. The following are the immediate actions taken to address this issue. 5/14/09

A. The Leadership team met, including the CEO, COO, CNO, ADQO, Infection Control Director, Peri-operative Manager, and Plant Operations Manager, and the decision was made to immediately suspend the use of the decontamination room and SPD area at Rancho Springs Medical Center.

B. The instruments currently being processed or stored in that area will be re-processed prior to use. They will be processed in an SPD area at Inland Valley Medical Center.

C. The surgeries in progress will continue. In the three operating rooms, the expected time to complete all cases is one hour.

D. The instruments from these cases will be cleaned of their bio-burden per the usual process of manual cleaning and the ultrasonic washer. The instruments will be fully processed in an SPD area at Inland Valley Medical Center.

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was observed on May 11, 2009, at 1:20 p.m. The refrigerator contained the following medications:

1. One Integrelin 0.75mg/ml 100 ml vial (to prevent blood clots in cardiac patients);
2. Five diltiazem 25mg/5ml, 5ml vials (to treat abnormal cardiac rhythms);
3. Six diltiazem 25mg/5ml, 10ml vials (to treat abnormal cardiac rhythms);
4. two diltiazem 5mg/ml, 25ml vials (to treat abnormal cardiac rhythms);
5. Ten Brovanna inhalation solution 2ml (to improve lung function);
6. Six Pulmozyme 2.5ml (to improve lung function);
7. Nine desmopressin acetate 4mcg/ml, 1ml (for treatment of DI);
8. Five aspirin suppositories 300mg (for pain and fever);
9. Two tobramycin inhalation solution 300mg/5ml (to treat lung infections);
10. Azithromycin 500mg/250ml of D5W (an IV antibiotic);
11. Amikacin 825mg/100ml of NS (an IV antibiotic);
12. Ceftriaxone 1gm/50ml of D5W (an IV antibiotic);
13. Two tigecycline 50mg/50ml premix (an IV antibiotic); and,
15. Norepinephrine 4 mg/500ml (to increase blood pressure).

According to the manufacturer's recommendations for the medications stored in the PCU refrigerator, the medications should be stored between 36° F and 46° F.

The manufacturer's recommendations for diltiazem indicate the medication should not be frozen.

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E. The OR Manager will contact the physicians who have cases scheduled for the remainder of the day to discuss moving them to Inland Valley Medical Center or rescheduling them for a later day.

F. By 2:00pm, the three cases in progress had finished and all subsequent elective cases had been moved to Inland Valley or rescheduled.

G. The hospital is also exploring the possibility of an outside contractor who can process instruments from the Rancho Springs campus.

H. This plan was presented and accepted by the CDPH/CMS Survey Team. The hospital was granted a temporary program flex waiver.

5. Over the course of the next five days, the hospital mobilized a multidisciplinary team that consisted of SWHCS Plant Operations, UHS Design & Construction, third party engineers and an OSHPD Inspector of Record to effect the necessary repairs to ensure an adequate air flow in the perioperative area to meet the current regulatory requirements. OSHPD performed an inspection, approved the repairs and signed off on the substantial completion of the project.

6. The perioperative spaces were terminally cleaned under the supervision of the Perioperative Manager and the Infection Control Coordinator. The hospital notified CDHP that the repairs had been completed; the area cleaned and requested to reopen the OR's, SPD and the SPD/Decontamination areas. The sterilizer was run empty for full cycles to verify that the ventilation system maintained the proper temperature and humidity levels while the equipment was in use; the area temperature and humidity levels were logged and noted to be within the acceptable ranges. On 5/21/09, a CDPH surveyor inspected the area and provided feedback to the District Office who then discontinued the Temporary Program Flex initiated on 5/14/09 and granted the request to reopen the perioperative areas.

5/19/09

5/22/09

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On May 11, 2009, at 2 p.m., the survey team requested the documented alerts and corrective actions for the last 30 days. No alerts or corrective action had been provided to the survey team by 5 p.m. on May 11, 2009.

During an interview with the DOP on May 1, 2009, at 2:30 p.m., the DOP stated he had not received notification regarding medication refrigerators being out of range since the implementation of the TAS. The DOP stated he was not aware the PCU refrigerator was at freezing levels. He stated the medications could not be guaranteed to be effective if they had been stored below the manufacturer's recommendations (36° F). He stated the medications should have been discarded.

During an interview with the director of laboratory services on May 11, 2009, at 3:10 p.m., the director stated when the TAS system was implemented, she continued to monitor the laboratory refrigerators with her current manual system and document on a daily log. She stated she did not have computer access to the TAS and the system was not reliable enough to monitor the laboratory refrigerators, which contained blood products and patient specimens that were stored for up to a week.

On May 11, 2009, at 4:15 p.m., the HS1 stated she had worked in the hospital for over 16 years and is a HS at both campuses. HS1 stated she had attended training prior to implementation of the system which included PowerPoint slides.

A review of the PowerPoint presentation showed it was an overview of the system features and capabilities. The presentation slides did not

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7. The temperature and humidity parameters were aligned with the appropriate industry and regulatory requirements. 5/22/09

Temperature Range: 68°F - 73°F (Ref: AIA)
Humidity Range: 35% - 60% (Ref: NFPA)

8. The Surgical Services Director drafted a policy, Temperature and Humidity, Periop to formalize the perioperative temperature and humidity monitoring process. This policy provides the information regarding the daily logging of temperature/humidity in the perioperative areas and the steps to take should there be a reading that is out-of-range. Input for the policy was provided by the Directors for Women's Services and Infection Control and by Plant Operations. The policy was approved by the Board of Governors. 7/28/09

9. The Infection Control Director revised the policy, Surveillance, Infection Control to include an example of targeted surveillance includes monitoring surgical cases if the perioperative temperature or humidity are out-of-range for two consecutive days. The policy was approved by the Infection Control Committee and the Board of Governors. 7/28/09

10. The Associate Administrator and the Plant Operations Manager reviewed and revised the policy, Control of Hospital Temperature to include the proper ranges for the perioperative areas and to enhance the wording regarding the need to document actions taken if the department is notified about an out-of-range value. The policy was approved by the Board of Governors. 7/28/09

11. The Associate Administrator and the Plant Operations Manager reviewed and revised the policy, Work Order Requests to include the information regarding the hospital's on-line work order request process. The policy was approved by the Board of Governors. 7/28/09

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provide information or staff instructions on how to implement and use the system within the facility. The HS1 confirmed she had not been provided information on how to use the system within the hospital.

Upon further questioning, HS1 stated she had not received any temperature alerts at the RSMC campus recently and "perhaps" one or two from IVMC.

During an interview with the SO on May 11, 2009, at 4:50 p.m., the SO stated he had not submitted any reports regarding the success or failure of the temperature monitoring system. He further stated he had not yet checked each refrigerator on the nursing units to verify whether the unit contained food or medications. The SO stated he realized the acceptable temperature ranges for food and medication were different, and there was a potential danger to patients if food was stored at medication ranges (too hot) and medication was stored at food ranges (too cold), but he had not, "had time," to ensure the correct ranges were assigned to each unit.

The CEO, COO, CNO, AA, and PI Director were notified Immediate Jeopardy was identified on May 11, 2009, at 5:40 p.m. The Immediate Jeopardy was identified due to the facility's failure to ensure temperature controls in pharmaceutical, food preparation, and other appropriate areas.

On May 11, 2009, at 7:52 p.m., an acceptable Immediate Plan of Correction was provided which included manual logging of temperatures used for patient food, and medications.

On May 11, 2009, starting at 6:30 p.m., a tour of the patient nourishment refrigerators was

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Monitoring
To ensure ongoing compliance in maintaining proper temperature and ventilation the hospital has done the following:

1. The Board of Governors is to receive a report at each regular meeting to verify that the hospital is taking appropriate actions to ensure that staff is following the revised hospital policies and procedures. Administration provides the Board an explanation for any variation and the steps taken to correct the issue. Upon achieving three consecutive months of 100% compliance in all areas, the Board will make a determination to what extent ongoing monitoring is to occur. 6/24/09

2. All refrigerator/freezer temperature logs and the perioperative temperature and humidity logs will be submitted on a monthly basis to each Director's Senior Team member. (Dietary – Associate Administrator. Pharmacy, Surgery and Women's Service – Chief Nursing Officer). The Administrator will review the log to ensure that daily logging has been done and if there is an out-of-range reading, the action taken to return the unit/area to the proper range is documented. The data will be aggregated and reported to the PI/RM Committee for analysis, issue identification and action planning as appropriate. The information is to forward to the BOG at each of their regular meeting. PI Indicators:
Daily checks are to be done and documented – Goal: 100% Compliance.
Action is taken for every out-of-range reading and documented appropriately – Goal: 100% Compliance. 7/1/09

3. Each monitoring department has included the temperature and humidity process in their PI activities, with indicators identified. 7/1/09

4. Reports on the monitoring of this plan of correction will also forward to the Environment of Care Committee. The P&T Committee will receive the report regarding patient nourishment and medication refrigerator/freezers. The Infection Control Committee will receive the 7/1/09

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conducted at RSMC campus. Four of four patient nourishment refrigerators had no secondary thermometer. Two of the four nourishment refrigerators contained milk at temperatures of 42.2° and 43.5° F. The NSD stated the refrigerator/freezer units on the patient units did not contain a secondary thermometer because staff had been told they were not needed and were instructed to remove them.

On May 11, 2009, at 6:50 p.m., FSW 1 stated she was responsible for stocking the patient unit refrigerators on a daily basis. FSW 1 stated she started stocking the units that day at 3:15 p.m. FSW 1 stated nourishment refrigerators used to contain a secondary thermometer which she would use to spot check and verify the refrigerator/freezers were working. The FSW 1 stated she had not seen the manual thermometers for approximately six weeks or so.

On May 12, 2009, at 2:15 p.m., a carton of milk in the RSMC ICU nourishment refrigerator was found to be 44.9°F.

On May 11, 2009, at 6:40 p.m., RN 1 and 2 stated, while there was currently no breast milk on the unit, it was their practice to throw out breast milk if the refrigerator temperature was greater than 39° F. The unit RNs stated there was no way to verify if the TAS monitoring device in the breast milk refrigerator was on and working. There was no secondary thermometer in the refrigerator.

On May 12, 2009, at 9:55 a.m., a second request was made to the AA regarding all the alerts and corrective actions taken by the facility in the last 30 days resulting from TAS alerts.

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report regarding the perioperative areas.

5. The Chief Operating Officer is to ensure that air duct cleaning is a budgeted annual expense. 7/1/09

6. Infection Control rounds in the perioperative area include a check of the perioperative temperature and humidity logs. 7/14/09

Persons Responsible:
Daily Monitoring: Dietary, Pharmacy, Surgical & Women's Services Directors
Documentation of Actions if Out-of-Range
Reading: Plant Operations Manager
Oversight and Reporting: Associate Administrator and Chief Nursing Officer

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The following alert and corrective action information was provided by the SO:

1. RSMC dietary refrigerator alerted on April 20, 2009, at 11:17 a.m., continuously below minimum range, alerts sent to IS and Plant Ops, corrective action done May 11, 2009 (21 days later);
2. IVMC OB refrigerator 4 alerted on April 13, 2009, at 10:07 a.m., continuously below minimum range, alerts sent to IS and Plant Ops, corrective action done May 11, 2009 (28 days later).
3. RSMC OR refrigerator alerted on April 23, 2009, at 7:44 p.m., no sensor contact since April 23, 2009, at 5:43 p.m., alerts sent to IS and Plant Ops, corrective action was done and the unit was working on May 11, 2009 (18 days later).
4. RSMC PACU PF - refrigerator/freezer alerted on April 23, 2009, at 7:46 p.m., with no sensor contact since April 23, 2009, alert sent to system, transmitter was checked and working on May 11, 2009 (18 days later).
5. IVMC - L&D freezer alerted May 8, 2009, at 11:51 p.m., with no sensor contact since May 8, 2009, at 9:50 p.m., alert sent to system, transmitter checked and working on May 11, 2009 (3 days later).
6. IVMC 2C freezer alerted on April 21, 2009, at 7:10 a.m., continuously below minimum since April 21, 2009, alerts sent to system, corrective action was not done until May 11, 2009 (20 days later).
7. a. RSMC - ED patient refrigerator alerted on April 23, 2009, at 7:45 p.m., no sensor contact since April 23, 2009, alert E-mail sent to system,

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transmission checked and found working on May 11, 2009 (18 days later).

b. RSMC - ED patient refrigerator alerted on April 26, 2009, at 1:59 p.m., continuously above maximum since April 26, 2009, alerts sent to system, corrective action not done until May 11, 2009 (15 days later).

c. RSMC - ED Refrigerator #2 alerted on May 11, 2009, at 7.48 p.m., no sensor contact since April 23, 2009, alerts sent to IS and Plant Ops, transmission checked and working on May 11, 2009 (18 days later).

d. RSMC - ED refrigerator #1 alerted on April 23, 2009, at 7:52 p.m., no sensor contact since April 23, 2009, at 5:52 p.m., alerts sent to IS and Plant Ops, transmission had been checked and is working on May 11, 2009 (18 days later).

The corrective actions did not include notification of the department managers or the disposition of the product contained in the refrigerators or freezers.

A comparison of the TAS graphs and alerts for the 30 day period was conducted. The TAS graph for the IVMC Dietary Food Refrigerator 4 showed it had been consistently above the 40° F maximum for the entire 30 day period. There was no alert or corrective action report provided to the survey team.

Additional TAS graphs showed refrigerators with temperatures consistently outside of the maximum and minimum criteria ranges during the 30 day period as follows:

1. RSMC Dietary Refrigerator 2;
2. RSMC PCU Refrigerator 1;

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- 3. RSMC Cardio Refrigerator 1;
- 4. RSMC ED Refrigerator 2;
- 5. RSMC ICU Refrigerator 1;
- 6. RSMC ICU Refrigerator 2;
- 7. IVMC OR Refrigerator 5;
- 8. IVMC Lab Refrigerator 5;
- 9. IVMC Lab Refrigerator 4;
- 10. IVMC OB Refrigerator 4; and,
- 11. IVMC 2West Refrigerator 4.

Of the five IVMC refrigerators identified by the 30 day graph, only one alert dated April 13, 2009 corresponded with the IVMC TAS graphs (IVMC OB Refrigerator 4). Corrective action was entered into the system on May 11, 2009, 28 days later and after the survey team had identified the problem. The TAS graph showed the unit consistently ran outside of the criteria after the alert date.

Of the six RSMC refrigerators identified by the 30 day graph, only one alert dated April 23, 2009, corresponded with the RSMC TAS graphs (RSMC ED Refrigerator 2). Corrective action was entered into the system on May 11, 2009, 18 days later and after the survey team had identified the problem. The TAS graph showed the unit had consistently ran outside of the criteria after the alert date.

During an interview with HS 2 On May 12, 2009, at 1:30 p.m., HS2 stated she was informed of

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implementation of the new electronic temperature monitoring from reading a memo. The HS stated she did not receive a facility in-service on the new monitoring system. HS 2 also stated, when there was a system alert indicating a temperature was out of range, she would do a physical inspection of the refrigerator and notify plant ops if she could not resolve the problem. The HS stated that she did not notify the DSM or DOP when medication or food refrigerators were out of range. She stated she was not aware of an existing facility policy on what to do in case of system alerts.

During an interview with the PI Director on May 12, 2009, at 1:40 p.m., the PI Director stated there were no sign in sheets to indicate the HSs received training on the new system. The PI Director also confirmed the system went live in September 2008. According to the minutes of the, "Operational PI Committee," dated September 9, 2008, the validation of the system prior to implementation took longer than expected. The PI Director stated there was no data collected or analyzed to confirm the system's accuracy during the validation phase. The PI Director stated the presentation included, "verbal data" and there was no specific data presented.

On May 12, 2009, at 2:30 p.m., the PI Director stated the SO had presented the EOC PI plan to the GB on July 28, 2008. According to the GB minutes, the EOC Proposed PI Indicators included monitoring of the TAS system. The PI Director was asked to provide the data submitted to date. The PI Director stated she had not received any PI data since the implementation of the system.

The TAS graph displaying 30 days of temperature and humidity monitoring for the OB CS room was

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reviewed on May 13, 2009. The log indicated between April 15 and April 20, 2009, the humidity in the room was averaging below 30%.

During a tour of the OB CS room on May 13, 2009, at 11:10 a.m., the hygrometer (instrument used to measure relative humidity) on the wall showed the humidity measured 64%. A document titled, "Women's Services Temperature/Humidity Log, OR," for the month of May 2009 was observed hanging on the wall. A review of the document indicated the temperature and humidity were being manually recorded each day. Further review of the log indicated 12 of 13 days in May had humidity values of >60%. The log indicated the correct range for humidity was 30-60%, and if it was out of range, the staff was to contact plant ops. Logs for March, April, and May 2009 were requested for review.

The values recorded on the logs indicated the following:

1. March 5, 2009, humidity 62%, no corrective action taken, there was no evidence the humidity was rechecked that day;
2. March 19, 2009, humidity 69%, no corrective action taken, there was no evidence the humidity was rechecked that day;
3. March 21, 2009, humidity 67%, no corrective action taken, there was no evidence the humidity was rechecked that day;
4. March 22, 2009, humidity 61%, no corrective action taken, there was no evidence the humidity was rechecked that day;
5. March 30, 2009, humidity 61%, no corrective

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A 726	<p>Continued From page 38</p> <p>action taken, there was no evidence the humidity was rechecked that day;</p> <p>6. April 23, 2009, humidity 61%, no corrective action taken, there was no evidence the humidity was rechecked that day;</p> <p>7. April 24, 2009, humidity 65%, no corrective action taken, there was no evidence the humidity was rechecked that day;</p> <p>8. April 25, 2009, humidity 62%, no corrective action taken, there was no evidence the humidity was rechecked that day;</p> <p>9. May 1, 2009, humidity 62%, no corrective action taken, there was no evidence the humidity was rechecked that day;</p> <p>10. May 2, 2009, humidity 67%, no corrective action taken, there was no evidence the humidity was rechecked that day;</p> <p>11. May 3, 2009, humidity 67%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day;</p> <p>12. May 4, 2009, humidity 67%, no corrective action taken, there was no evidence the humidity was rechecked that day;</p> <p>13. May 6, 2009, humidity 65%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day;</p> <p>14. May 7, 2009, humidity 65%, no corrective action taken, there was no evidence the humidity was rechecked that day;</p>	A 726		
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15. May 8, 2009, humidity 62%, no corrective action taken, there was no evidence the humidity was rechecked that day;

16. May 9, 2009, humidity 65%, no corrective action taken, there was no evidence the humidity was rechecked that day;

17. May 10, 2009, humidity 66%, no corrective action taken, there was no evidence the humidity was rechecked that day;

18. May 11, 2009, humidity 65%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day;

19. May 12, 2009, humidity 62%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day; and,

20. May 13, 2009, humidity 66%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day.

The manual log indicated there were five of 31 days in March, three of 30 days in April, and 12 of 13 days in May 2009 with the humidity >60%

There was no evidence on the manual log the humidity was below 30% at any time from April 15 through April 20, 2009, which was inconsistent the TAS.

The OB CS room log was reviewed on May 13, 2009. The log indicated the following:

CA DEPT OF
PUBLIC HEALTH
09 JUL 31 PM 3:37
LICENSING & CERT.
RIVERSIDE COUNTY

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1. March 5, 2009, two CSs performed when the humidity was 62%;
2. March 19, 2009, six CSs performed when the humidity was 69%;
3. March 21, 2009, one CS performed when the humidity was 67%;
4. March 30, 2009, one CS performed when the humidity was 61%;
5. April 23, 2009, two CSs performed when the humidity was 61%;
6. April 25, 2009, one CS performed when the humidity was 62%;
7. May 1, 2009, two CSs performed when the humidity was 62%; and,
8. May 2, 2009, two CSs performed when the humidity was 67%.

The log indicated there were 10 CSs in March, three CSs in April, and two CSs in May 2009 performed when the humidity of the OB CS room was >60%.

During an interview with RN 2 on May 13, 2009, at 11:15 a.m., the RN stated she notified plant ops about the high humidity that day.

During an interview with the SSM on May 13, 2009, at 11:35 a.m., the SSM stated she had not been notified of temperatures or humidities that were out of range in any of the perioperative areas since the TAS system was implemented.

During a concurrent interview with the ICD and

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A 726 Continued From page 41

the RSMC POD on May 13, 2009, at 1:20 p.m., the ICD stated he had been checking with the SO on a regular basis to see if there were any temperature or humidity issues in the perioperative areas. The ICD stated the SO was getting his information from the TAS, so he was told there were no values out of range. The POD stated he did not rely on the TAS, but instead he relied on the thermometer and hygrometer inside the rooms for the correct values. The POD stated the OB CS room had, "been a problem since I started here (approximately one year ago)." The POD stated the building was old and they had a hard time regulating the temperature and humidity. The POD stated when the plant ops staff was called regarding the humidity being too high in the OB CS room; they would cool the room, then slowly increase the temperature and warm the room to evaporate off the humidity. The POD stated he was not able to provide evidence of corrective action done by his staff, as he had no system in place to track work orders or verify their completion.

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The TAS log displaying a 30 day graph for the SPD room was reviewed on May 13, 2009. The log indicated between April 25 and May 1, 2009, the temperature was averaging 77° F and the humidity was averaging 78%. According to the TAS criteria, the acceptable temperature range was 68-73° F and the acceptable humidity range was 30-60%.

The facility detail summary of temperatures and humidity for the SPD room for May 1 through 12, 2009, was reviewed on May 13, 2009. The summary indicated the humidity was >60% on 119 of 1195 readings (10% of the time).

During a tour of the SPD room on May 13, 2009,

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A 726	<p>Continued From page 42</p> <p>at 11:40 a.m., the TAS monitoring device was observed in the room. There was no secondary thermometer or hygrometer measuring temperature and humidity in the room.</p> <p>During a review of the TAS graphs on May 13, 2009, no graph was found for the decontamination room (where surgical instruments are cleaned), indicating there was no monitoring of temperature or humidity in the room.</p> <p>Immediately upon entering the decontamination room on May 13, 2009, at 11:45 a.m., the room was noted to be hot and humid. There was no TAS monitoring device in the room. There was no thermometer or hygrometer in the room measuring the temperature and humidity.</p> <p>The IC rounds reports were reviewed on May 13, 2009. The report dated February 4, 2009, indicated, "decontamination room temperature and humidity are excessive in accordance with high/low limits." (The same report, received from the PI Director on May 14, 2009, at 10:05 a.m., appeared to be an exact replica of the original report received, except the information regarding the decontamination room was omitted/not present).</p> <p>The report dated February 6, 2009, indicated in the decontamination room, "two hydrometers on wall with different readings. One hygrometer is digital, one is analog. Both are mounted within six or seven inches from each other, varying by approximately 20% humidity reading...."</p> <p>The report dated February 11, 2009, indicated, "decon (decontamination) room has elevated temperature above range limitations." (The same</p>	A 726		
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report, received from the PI Director on May 14, 2009, at 10:05 a.m., appeared to be an exact replica of the original report received, except the information regarding the decontamination room was omitted/not present).

The report dated March 10, 2009, indicated, "decon room temperature and humidity out of range."

The report dated April 21, 2009, indicated, "decontamination room - open hole in wall from previous thermostat repair/relocation. Mold is also evident on ceiling of this room (next to sterilizer) due to excessive humidity."

During an interview with the ICD on May 13, 2009, at 2:10 p.m., the ICD stated the IC rounds reports were sent to all of senior management (including the CEO, COO, CNO, and the PI Director) and to all department managers where an issue was identified.

According to the 2008 AORN Perioperative Standards and Recommended Practices:

1. the quality of air entering the operating rooms should be carefully controlled;
2. temperature should be maintained between 68° F and 73° F within the operating room suite and general work areas in sterile processing (OB CS room and SPD);
3. the decontamination area temperature should be maintained between 60° F and 65° F;
4. the relative humidity should be maintained between 30% and 60% within the perioperative suite, including the instrument processing areas

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	and sterilizing areas (OB CS room, SPD, and decontamination room); and,			
	5. high humidity increases the risk of microbial growth in areas where sterile supplies are stored or procedures are performed.			
	<p>During an interview with the RSMC POD on May 13, 2009, at 1:20 p.m., the POD stated the ducts in the HVAC system needed to be cleaned, and that would help with the temperature and humidity problems. The POD stated the previous POD requested duct cleaning in 2008 for the 2009 capital budget, but it was not approved. The POD stated he requested it again for the in 2009 for the 2010 capital budget, but the budget had not yet been completed so he did not know if it would be approved.</p>			
	<p>The facility's fiscal year 2009 capital budget request documents for the plant ops department were reviewed on May 13, 2009. The documents indicated facility air duct cleaning was requested by the previous POD, to be completed in 2009. The documents indicated the previous POD wrote a justification for the duct cleaning, including, "we need to budget a similar amount each year to maintain a safe environment of care for our patients."</p>			
	<p>The 2009 capital budget summary was reviewed on May 13, 2009. The summary indicated the duct work was not approved for completion in 2009.</p>			
	<p>On May 13, 2009, at 3:40 p.m., the CEO, COO, CNO, AA, and PI Director were notified of the findings related to temperature and humidity monitoring in the perioperative areas, and an updated immediate POC was requested to</p>			

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A 726	<p>Continued From page 45 include these.</p> <p>An acceptable POC was received on May 13, 2009, at 8:15 p.m. The POC included purchasing new temperature and humidity monitors, placing a monitor in each perioperative area, implementing a manual log for daily checks to be performed by the charge nurse, and notification of plant ops if any temperatures or humidities were out of range.</p> <p>During a tour of the OR decontamination room at RSMC on May 14, 2009, at 7:53 a.m., accompanied by the SSM and the RSMC POD, both stated the temperature and humidity were difficult to maintain in the room. The SSM stated it was, "an ongoing problem."</p> <p>A review of the OR temperature and humidity logs indicated the decontamination room was 78.5° F at 7:30 p.m. the night before (May 13, 2009). The log further indicated the temperature of the room was 75.4° F at 6:30 that morning. The current temperature in the room was within the acceptable range.</p> <p>During an interview with the RSMC POD on May 14, 2009, at 9:05 a.m., the POD stated the air ducts needed to be cleaned, as the volume of air going through the ducts decreased when they became dirty, leading to less cooling with higher temperatures and humidity. The POD stated he had told his direct supervisor (the AA), "about three times." He stated his supervisor told him to, "just balance it the best you can."</p> <p>During a revisit to the OR on May 14, 2009, at 10:45 a.m., upon entering the decontamination room, the room was noted to be hot and humid. The thermometer/hygrometer was observed with</p>	A 726		
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a temperature of 80.1° F and a humidity of 65%. An employee was observed cleaning surgical instruments in the room. The thermometer/hygrometer in the SPD was observed with a temperature of 74.7° F. A tour of the OR indicated all three rooms had surgical cases in progress.

A 726

On May 14, 2009, at 10:50 a.m., Engineer 2 was observed in the OR area. The engineer stated he was aware of the temperature and humidity in the decontamination room and was, "working on it." The engineer stated with the system they had in the facility, they had to heat the room before they could begin the cooling process.

On May 14, 2009, at 11:42 a.m., the SSM and PI Director were notified of the findings related to the temperature and humidity in the decontamination room and the temperature in SPD, and an updated immediate POC was requested.

During an interview with Engineer 1 at IVMC on May 14, 2009, at 12:45 p.m., the engineer stated the RSMC facility was not meant to be a hospital, it was built as a SNF and there were different airflow requirements for SNFs than there were for hospitals. The engineer stated he was called to the facility a couple of times a week to correct temperature and humidity problems. The engineer stated there was not adequate ventilation out of the room around the sterilizer area, so when the sterilizer was used, the room would get hot and humid. The engineer stated there was, "no way," to control the temperature and humidity in the perioperative area at RSMC, and he was concerned about patient safety. He stated he had, "spouted off," to the RSMC POD and the COO, but nothing had been done to correct the problem.

09 JUL 31 PM 3:37
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An acceptable POC was received on May 14, 2009, at 3 p.m. The plan included the following:

1. suspending the use of the decontamination room at RSMC;
2. reprocessing all of the instruments that were stored at RSMC;
3. completing the cases in progress at RSMC, then moving the remaining cases to IVMC;
4. cleaning the instruments in use at RSMC of their bioburden (blood and tissue), then processing them at IVMC; and,
5. exploring the possibility of having an outside contractor process the instruments for RSMC.

On May 14, 2009, at 4:03 p.m., the CNO and PI Director stated they needed to have engineers get into the ceiling above the RSMC OR, and they did not want surgical cases to be done while this was happening. The CNO and PI Director requested a program flex from the Department to close the RSMC ORs and have two CCT ambulances standing by at RSMC to transfer patients needing surgery to IVMC.

The program flex was granted by the Department at 4:41 p.m. on May 14, 2009.

On May 14, 2009, at 5:05 p.m., after the team verified the following:

1. refrigerator and freezer temperatures were being checked and logged manually by staff at both campuses;

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2. all refrigerator and freezer temperatures were within acceptable range at both campuses;
3. temperature and humidity in the OB CS room at RSMC and in the perioperative areas at IVMC were being checked and logged manually by staff;
3. temperature and humidity in the OB CS room at RSMC were within acceptable ranges;
4. temperature and humidity in the perioperative areas at IVMC were within acceptable ranges;
5. the RSMC OR was not in use;
6. the surgical instruments that were stored at RSMC were being reprocessed at IVMC; and,
7. all surgical cases were being done at IVMC (with the exception of emergency CSs at RSMC);

the CEO, GBM 1, COO, CNO, AA, MD, and PI Director were notified the Immediate Jeopardy was abated.

A 940 482.51 SURGICAL SERVICES

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

This Condition is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure ventilation and temperature controls in the perioperative areas (SPD, decontamination, and OB CS room) at the

A 726 Continued from page 48

A 940 Surgical Services

It is the policy of Southwest Healthcare System to ensure proper ventilation and temperature controls in the perioperative areas of SPD, decontamination, and OB CS room on the RSMC campus. The following actions were taken to assure an effective implementation of the Plan of Correction:

1. Immediate Action: The hospital took the following actions. 5/13/09

Effective 05/13/2009, the hospital reinstated a manual log for temperature and humidity levels in operating rooms, SPD and the decontamination room at Rancho Springs Medical Center.

A. The hospital purchased six (6) new temperature/humidity monitors for the:

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RSMC campus were in accordance with accepted standards of practice, resulting in mold growth in the decontamination room and the potential for infection in patients undergoing surgical procedures.

The cumulative effect of this systemic problem resulted in failure to ensure the provision of safe surgical services.

Findings:

During an investigation of the effectiveness of a newly implemented wireless temperature monitoring system (TAS) on May 13, 2009, at 9 a.m., it was noted the system was also being used to monitor the temperature and humidity in the perioperative areas at RSMC.

The TAS graph, displaying 30 days of temperature and humidity monitoring for the OB CS room, was reviewed on May 13, 2009. The log indicated, between April 15 and April 20, 2009, the humidity in the room was averaging below 30%.

During a tour of the OB CS room on May 13, 2009, at 11:10 a.m., the hygrometer (instrument used to measure relative humidity) on the wall showed the humidity measured 64%. A facility document titled, "Women's Services Temperature/Humidity Log, OR," for the month of May was observed hanging on the wall. A review of the document indicated the temperature and humidity were being manually recorded each day. Further review of the log indicated 12 of 13 days in May had humidity values of >(above) 60%. The log indicated the correct range for humidity was 30-60%, and if it was out of range, the staff was to contact plant ops. Logs for March, April, and

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i. Four operating rooms (three in the main OR and one in the OB area)

ii. SPD area

iii. Decontamination room.

B. Daily, the Charge Nurse in the designated area will record the room temperature and humidity level on the log. On 05/13/09, the Chief Nursing Officer educated the Surgery and OB Nurse Directors regarding this process. The Surgery and Women's Directors/Managers are responsible for assuring that the Charge Nurse completes the daily documentation of room temperature and humidity.

i. The acceptable range for room humidity is 30% to 60%.

ii. The acceptable range for room temperature are as follows:

- Operating Room and SPD 68°F - 73°F
- Decontamination Area 60°F - 65°F

C. If any reading is out-of-range, the Charge Nurse will contact Plant Operations to assess the situation.

D. The Plant Operations engineer will take necessary action to correct the problem.

i. Actions taken by the Plant Operations staff will be documented on the log.

ii. Additional documentation will be maintained by the Plant Operations Department as necessary.

E. As the Charge Nurse performs the daily checks, if there are two consecutive days in which the temperature and/or humidity exceed the maximum threshold, in addition to contacting Plant Operations, the Charge Nurse will notify the Infection Control Director. The Infection Control Director will initiate appropriate tracking of surgical patients.

Infection Control

A. The operating rooms are terminally cleaned on a daily basis. Previously, the SPD and decontamination rooms were terminally cleaned a weekly basis, however on 05/07/09, based upon the recommendation of the Infection Control Director, the Chief Operating Officer directed that

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May 2009 were requested for review.

The values recorded on the logs indicated the following:

1. March 5, 2009, humidity 62%, no corrective action taken, there was no evidence the humidity was rechecked that day;
2. March 19, 2009, humidity 69%, no corrective action taken, there was no evidence the humidity was rechecked that day;
3. March 21, 2009, humidity 67%, no corrective action taken, there was no evidence the humidity was rechecked that day;
4. March 22, 2009, humidity 61%, no corrective action taken, there was no evidence the humidity was rechecked that day;
5. March 30, 2009, humidity 61%, no corrective action taken, there was no evidence the humidity was rechecked that day;
6. April 23, 2009, humidity 61%, no corrective action taken, there was no evidence the humidity was rechecked that day;
7. April 24, 2009, humidity 65%, no corrective action taken, there was no evidence the humidity was rechecked that day;
8. April 25, 2009, humidity 62%, no corrective action taken, there was no evidence the humidity was rechecked that day;
9. May 1, 2009, humidity 62%, no corrective action taken, there was no evidence the humidity was rechecked that day;

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terminal cleaning of SPD and the decontamination room be done on a daily basis.

B. Within the next 24-hours, the Infection Control Director will round with the EVS Manager in all operating rooms and the SPD and decontamination rooms to visually inspect them for cleanliness. Should any concern be identified, immediate action will be taken as directed by the Infection Control Director. If necessary, the use of the room will be suspended until cleared by Infection Control.

C. Upon notification by the Charge Nurse of an operating room, SPD or decontamination room exceeding the maximum threshold of temperature and/or humidity, the Infection Control Director will initiate targeted surveillance of surgical cases.

2. The CNO assigned the responsibility for daily monitoring of perioperative temperature and humidity to the Surgical Services and Women's Services Directors. The Directors instructed their staff to resume their previous role of monitoring the perioperative area temperature/humidity levels and to notify Plant Operations if a reading was noted to be out-of-range. The Manager of Plant Operations reminded the engineering staff of their responsibility to respond immediately and document the actions taken to return the area to the proper range on the log. The appropriate Director is to be notified by Plant Operations if the area requires more than a minor adjustment to allow the Director to assess the situation and take the necessary action to ensure patient safety.

3. Purchased and installed new digital thermometers/hygrometers in the four operating rooms, SPD and the SPD/Decontamination areas at Rancho Springs. 5/13/09

4. After replacing the temperature and humidity monitors in the Rancho Springs peri-operative area, it was noted this morning that the temperature and humidity in the decontamination and SPD rooms was out-of-range. Plant Operations was notified and despite their efforts, the decontamination room in particular 5/14/09

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- 10. May 2, 2009, humidity 67%, no corrective action taken, there was no evidence the humidity was rechecked that day;
- 11. May 3, 2009, humidity 67%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day;
- 12. May 4, 2009, humidity 67%, no corrective action taken, there was no evidence the humidity was rechecked that day;
- 13. May 6, 2009, humidity 65%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day;
- 14. May 7, 2009, humidity 65%, no corrective action taken, there was no evidence the humidity was rechecked that day;
- 15. May 8, 2009, humidity 62%, no corrective action taken, there was no evidence the humidity was rechecked that day;
- 16. May 9, 2009, humidity 65%, no corrective action taken, there was no evidence the humidity was rechecked that day;
- 17. May 10, 2009, humidity 66%, no corrective action taken, there was no evidence the humidity was rechecked that day;
- 18. May 11, 2009, humidity 65%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day;

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could not be brought into range. The following are the immediate actions taken to address this issue.

- A. The Leadership team met, including the CEO, COO, CNO, ADQO, Infection Control Director, Peri-operative Manager, and Plant Operations Manager, and the decision was made to immediately suspend the use of the decontamination room and SPD area at Rancho Springs Medical Center.
- B. The instruments currently being processed or stored in that area will be re-processed prior to use. They will be processed in an SPD area at Inland Valley Medical Center.
- C. The surgeries in progress will continue. In the three operating rooms, the expected time to complete all cases is one hour.
- D. The instruments from these cases will be cleaned of their bio-burden per the usual process of manual cleaning and the ultrasonic washer. The instruments will be fully processed in an SPD area at Inland Valley Medical Center.
- E. The OR Manager will contact the physicians who have cases scheduled for the remainder of the day to discuss moving them to Inland Valley Medical Center or rescheduling them for a later day.
- F. By 2:00pm, the three cases in progress had finished and all subsequent elective cases had been moved to Inland Valley or rescheduled.
- G. The hospital is also exploring the possibility of an outside contractor who can process instruments from the Rancho Springs campus.
- H. This plan was presented and accepted by the CDPH/CMS Survey Team. The hospital was granted a temporary program flex waiver.

5. Over the course of the next five days, the hospital mobilized a multidisciplinary team that consisted of SWHCS Plant Operations, UHS Design & Construction, third party engineers and an OSHPD Inspector of Record to effect the necessary repairs to ensure an adequate air flow

5/19/09

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19. May 12, 2009, humidity 62%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day; and,

20. May 13, 2009, humidity 66%, plant ops was notified, there was no evidence corrective action was taken or the humidity was rechecked that day.

The manual log indicated there were five of 31 days in March, three of 30 days in April, and 12 of 13 days in May with the humidity > (above) 60%.

There was no evidence on the manual log the humidity was below 30% at any time from April 15 through April 20, 2009, which was inconsistent with the TAS.

The OB CS room log was reviewed on May 13, 2009. The log indicated the following:

1. March 5, 2009, two CSs performed when the humidity was 62%;
2. March 19, 2009, six CSs performed when the humidity was 69%;
3. March 21, 2009, one CS performed when the humidity was 67%;
4. March 30, 2009, one CS performed when the humidity was 61%;
5. April 23, 2009, two CSs performed when the humidity was 61%;
6. April 25, 2009, one CS performed when the humidity was 62%;

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in the perioperative area to meet the current regulatory requirements. OSHPD performed an inspection, approved the repairs and signed off on the substantial completion of the project.

6. The perioperative spaces were terminally cleaned under the supervision of the Perioperative Manager and the Infection Control Coordinator. The hospital notified CDHP that the repairs had been completed; the area cleaned and requested to reopen the OR's, SPD and the SPD/Decontamination areas. The sterilizer was run empty for full cycles to verify that the ventilation system maintained the proper temperature and humidity levels while the equipment was in use; the area temperature and humidity levels were logged and noted to be within the acceptable ranges. On 5/21/09, a CDPH surveyor inspected the area and provided feedback to the District Office who then discontinued the Temporary Program Flex initiated on 5/14/09 and granted the request to reopen the perioperative areas.

7. The temperature and humidity parameters were aligned with the appropriate industry and regulatory requirements.
Temperature Range: 68°F - 73°F (Ref: AIA)
Humidity Range: 35% - 60% (Ref: NFPA)

8. The Surgical Services Director drafted a policy, Temperature and Humidity, Periop to formalize the perioperative temperature and humidity monitoring process. This policy provides the information regarding the daily logging of temperature/humidity in the perioperative areas and the steps to take should there be a reading that is out-of-range. Input for the policy was provided by the Directors for Women's Services and Infection Control and by Plant Operations. The policy was approved by the Board of Governors.

9. The Infection Control Director revised the policy, Surveillance, Infection Control to include an example of targeted surveillance includes

5/22/09

5/22/09

7/28/09

7/28/09

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7. May 1, 2009, two CSs performed when the humidity was 62%; and,

8. May 2, 2009, two CSs performed when the humidity was 67%.

The log indicated there were 10 CSs in March, three CSs in April, and two CSs in May 2009, performed when the humidity of the OB CS room was >60%.

During an interview with RN 2 on May 13, 2009, at 11:15 a.m., RN 2 stated she notified plant ops about the high humidity that day.

During an interview with the SSM on May 13, 2009, at 11:35 a.m., the SSM stated she had not been notified of temperatures or humidities that were out of range in the perioperative areas since the TAS system was implemented.

During a concurrent interview with the ICD and the RSMC POD on May 13, 2009, at 1:20 p.m., the ICD stated he had been checking with the SO on a regular basis to see if there were any temperature or humidity issues in the perioperative areas. The ICD stated the SO was getting his information from the TAS, so he was told there were no values out of range. The POD stated he did not rely on the TAS, but instead he relied on the thermometer and hygrometer inside the rooms for the correct values. The POD stated the OB CS room had, "been a problem since I started here (approximately one year ago)." The POD stated the building was old and they had a hard time regulating the temperature and humidity. The POD stated when the plant ops staff was called regarding the humidity being too high in the OB CS room; they would cool the room, then slowly increase the temperature and

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monitoring surgical cases if the perioperative temperature or humidity are out-of-range for two consecutive days. The policy was approved by the Infection Control Committee and the Board of Governors.

10. The Associate Administrator and the Plant Operations Manager reviewed and revised the policy, Control of Hospital Temperature to include the proper ranges for the perioperative areas and to enhance the wording regarding the need to document actions taken if the department is notified about an out-of-range value. The policy was approved by the Board of Governors. **7/28/09**

11. The Associate Administrator and the Plant Operations Manager reviewed and revised the policy, Work Order Requests to include the information regarding the hospital's on-line work order request process. The policy was approved by the Board of Governors. **7/28/09**

Monitoring
To ensure ongoing compliance in maintaining proper temperature and ventilation the hospital has done the following:

1. The Board of Governors is to receive a report at each regular meeting to verify that the hospital is taking appropriate actions to ensure that staff is following the revised hospital policies and procedures. Administration provides the Board an explanation for any variation and the steps taken to correct the issue. Upon achieving three consecutive months of 100% compliance in all areas, the Board will make a determination to what extent ongoing monitoring is to occur. **6/24/09**

2. All perioperative temperature and humidity logs will be submitted on a monthly basis to the CNO. The CNO will review the logs to ensure that daily logging has been done and if there is an out-of-range reading, the action taken to return the unit/area to the proper range is documented. The data will be aggregated and reported to the PI/RM Committee for analysis, issue identification and action planning as **7/1/09**

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warm the room to evaporate off the humidity. The POD stated he was not able to provide evidence of corrective action done by his staff, as he had no system in place to track work orders or verify their completion.

The TAS log displaying a 30 day graph for the SPD room was reviewed on May 13, 2009. The log indicated, between April 25 and May 1, 2009, the temperature was averaging 77° F and the humidity was averaging 78%. According to the TAS criteria, the acceptable temperature range was 68-73° F and the acceptable humidity range was 30-60%.

The detail summary of temperatures and humidity for the SPD room for May 1 through 12, 2009, was reviewed on May 13, 2009. The summary indicated the humidity was >60% on 119 of 1195 readings (10% of the time).

During a tour of the SPD room on May 13, 2009, at 11:40 a.m., the TAS monitoring device was observed in the room. There was no secondary thermometer or hygrometer measuring temperature and humidity in the room.

During a review of the TAS graphs on May 13, 2009, no graph was found for the decontamination room (where surgical instruments are cleaned), indicating there was no monitoring of temperature or humidity in the room.

Immediately upon entering the decontamination room on May 13, 2009, at 11:45 a.m., the room was noted to be hot and humid. There was no TAS monitoring device in the room. There was no thermometer or hygrometer in the room measuring the temperature and humidity.

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appropriate. The information is to forward to the BOG at each of their regular meeting. PI Indicators:
Daily checks are to be done and documented – Goal: 100% Compliance.
Action is taken for every out-of-range reading and documented appropriately – Goal: 100% Compliance.

3. Each monitoring department has included the temperature and humidity process in their PI activities, with indicators identified. 7/1/09

4. Reports on the monitoring of this plan of correction will also forward to the Environment of Care Committee. The Infection Control Committee will receive the report regarding the perioperative areas. 7/1/09

5. The Chief Operating Officer is to ensure that air duct cleaning is a budgeted annual expense. 7/1/09

6. Infection Control rounds in the perioperative area include a check of the perioperative temperature and humidity logs. 7/1/09

Persons Responsible:
Daily Monitoring: Surgical & Women's Services Directors
Documentation of Actions if Out-of-Range Reading: Plant Operations Manager
Oversight and Reporting: Chief Nursing Officer

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The IC rounds reports were reviewed on May 13, 2009. The report dated February 4, 2009, indicated, "decontamination room temperature and humidity are excessive in accordance with high/low limits."

The report dated February 6, 2009, indicated in the decontamination room, "two hydrometers on wall with different readings. One hygrometer is digital, one is analog. Both are mounted within six or seven inches from each other, varying by approximately 20% humidity reading...."

The report dated February 11, 2009, indicated, "decon (decontamination) room has elevated temperature above range limitations."

The report dated March 10, 2009, indicated, "decon room temperature and humidity out of range."

The report dated April 21, 2009, indicated, "decontamination room - open hole in wall from previous thermostat repair/relocation. Mold is also evident on ceiling of this room (next to sterilizer) due to excessive humidity."

During an interview with the ICD on May 13, 2009, at 2:10 p.m., the ICD stated the IC rounds reports were sent to all of senior management (including the CEO, COO, CNO, and the PI Director) and to all department managers where an issue was identified.

According to the 2008 AORN Perioperative Standards and Recommended Practices:

1. the quality of air entering the operating rooms should be carefully controlled;

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2. temperature should be maintained between 68° F and 73° F within the operating room suite and general work areas in sterile processing (OB CS room and SPD);

3. the decontamination area temperature should be maintained between 60° F and 65° F;

4. the relative humidity should be maintained between 30% and 60% within the perioperative suite, including the instrument processing areas and sterilizing areas (OB CS room, SPD, and decontamination room); and,

5. high humidity increases the risk of microbial growth in areas where sterile supplies are stored or procedures are performed.

During an interview with the RSMC POD on May 13, 2009, at 1:20 p.m., the POD stated the ducts in the HVAC system needed to be cleaned, and that would help with the temperature and humidity problems. The POD stated the previous POD requested duct cleaning in 2008 for the 2009 capital budget, but it was not approved. The POD stated he requested it again for the in 2009 for the 2010 capital budget, but the budget had not yet been completed so he did not know if it would be approved.

The facility fiscal year 2009 capital budget request documents for the plant ops department were reviewed on May 13, 2009. The documents indicated facility air duct cleaning was requested by the previous POD, to be completed in 2009. The documents indicated the previous POD wrote a justification for the duct cleaning, including, "we need to budget a similar amount each year to maintain a safe environment of care for our

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The facility 2009 capital budget summary was reviewed on May 13, 2009. The summary indicated the duct work was not approved for completion in 2009.

During a tour of the OR decontamination room at RSMC on May 14, 2009, at 7:53 a.m., accompanied by the SSM and the RSMC POD, both stated the temperature and humidity were difficult to maintain in the room. The SSM stated it was, "an ongoing problem."

A review of the OR temperature and humidity logs indicated the decontamination room was 78.5° F at 7:30 p.m. the night before (May 13, 2009). The log further indicated the temperature of the room was 75.4° F at 6:30 that morning.

During an interview with the RSMC POD on May 14, 2009, at 9:05 a.m., the POD stated the air ducts needed to be cleaned, as the volume of air going through the ducts decreased when they became dirty, leading to less cooling with higher temperatures and humidity. The POD stated he had told his direct supervisor (the AA), "about three times." He stated his supervisor told him to, "just balance it the best you can."

During a revisit to the OR on May 14, 2009, at 10:45 a.m., upon entering the decontamination room, the room was noted to be hot and humid. The thermometer/hygrometer was observed with a temperature of 80.1° F and a humidity of 65%. An employee was observed cleaning surgical instruments in the room. The thermometer/hygrometer in the SPD was observed with a temperature of 74.7° F. A tour of the OR indicated all three rooms had surgical

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES A PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 050701	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 05/14/2009
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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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
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A 940	Continued From page 58 cases in progress.	A 940		
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On May 14, 2009, at 10:50 a.m., Engineer 2 was observed in the OR area. The engineer stated he was aware of the temperature and humidity in the decontamination room and was, "working on it." The engineer stated with the system they had in the facility, they had to heat the room before they could begin the cooling process.

On May 14, 2009, at 11:42 a.m., the SSM and PI Director were notified of the findings related to the temperature and humidity in the decontamination room and the temperature in SPD, and an updated immediate POC was requested.

During an interview with Engineer 1, at IVMC on May 14, 2009, at 12:45 p.m., the engineer stated the RSMC facility was not meant to be a hospital, it was built as a SNF and there were different airflow requirements for SNFs then there were for hospitals. The engineer stated he was called to the facility a couple of times a week to correct temperature and humidity problems. The engineer stated there was not adequate ventilation out of the room around the sterilizer area, so when the sterilizer was used, the room would get hot and humid. The engineer stated there was, "no way," to control the temperature and humidity in the perioperative area at RSMC, and he was concerned about patient safety. He stated he had, "spouted off," to the RSMC POD and the COO, but nothing had been done to correct the problem.