STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION
(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050110

(X2) MULTIPLE CONSTRUCTION
A. BUILDING ____________________________
B. WING ____________________________
(X3) DATE SURVEY COMPLETED 02/10/2017

NAME OF PROVIDER OR SUPPLIER
LOMPOC VALLEY MEDICAL CENTER
STREET ADDRESS, CITY, STATE, ZIP CODE
1515 E OCEAN AVENUE
LOMPOC, CA 93436

(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

A 023 482.11(c) LICENSURE OF PERSONNEL
A 023

INITIAL COMMENTS

The following represents the findings of the California Department of Public Health, Licensing and Certification, during a SAMPLE VALIDATION SURVEY conducted 2/6/17 through 2/10/17.

Representing the Department:
Surveyor 33720, HFEN
Surveyor 25092, HFEN
Surveyor 34445, HFEN Trainee
Medical Consultant, 20340
Dietary Consultant, 28773
Infection Control Consultant, 33399
Pharmacy Consultant, 13095
Pharmacy Consultant, 29359

The census was: 31
Patient records sampled: 33

The following 5 Conditions of Participation were NOT MET:
482.12-Governing Body
482.21-QAPI
482.25-Pharmaceutical Services
482.28-Food and Dietetic Services
482.42-Infection Control

A 023 482.11(c) LICENSURE OF PERSONNEL
A 023

The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

This STANDARD is not met as evidenced by:
Based on staff interview and departmental document review, the hospital failed to ensure that the Registered Dietitian (RD) position met applicable state certification requirements.

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

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (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.
The failure to ensure the registered dietitian provides guidance to the supervisor and staff of the dietetic service and is involved in planning and conducting in-service education programs can result in deficient practices that can negatively impact patients' health status.

Findings:

California Code of Regulations, Title 22, Division 5, Chapter 1, Article 3 specifies Dietetic Services Staff qualifications. The regulatory requirements for dietetic services specify the registered dietitian shall be employed on a full-time, part-time or consulting basis. Part-time or consultant services shall be provided on the premises at appropriate times on a regularly scheduled basis and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, patient counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus and participation in development or revision of dietetic policies and procedures and in planning and conducting in-service education programs.

On 2/8/17 at 10:15 a.m., an interview was conducted with the RD 4 regarding her role at the hospital. RD 4 stated she works part time and mostly sees the hospital inpatients and schedules outpatient referrals. The RD 4 stated she does meal rounds and cyber rounds. The RD 4 stated she used to do some trayline observations but has not done that in awhile since they had been working on revising policy and procedures. The RD 4 stated test trays are...
| A 023 | Continued From page 2
|       | done but not by her. She stated she was involved in menu planning and working on the nutrition analysis of the menus. The RD 4 stated she has not ever done any sanitation audits in the kitchen or provided any guidance to the supervisor.

On 2/9/17 at 9:22 a.m., an interview was conducted with RD 5 regarding her role at the hospital. RD 5 stated the clinical patients are the most important. RD 5 stated she was involved in updating policies and she helped analyze the menu when that was redone. RD 5 stated RD 4 checks more frequently then she does. RD 5 stated her boss is considered administration. RD 5 stated the DDS was really good at managing the kitchen so she does not get involved with that. RD 5 stated she attends staff meetings and they do some informal in-services with dietetic service staff. RD 5 stated she has no documentation of in-services they have done with the staff. RD 5 stated they also have a list of ideas about in-services for dietetic services but it has been on the back burner. RD 5 stated they can walk through the kitchen but she has not ever done any audits or looked at the sanitation practices of the kitchen and given guidance to the DDS.

Review of the RD job description, showed the RD is under the direct supervision of the Chief Nursing Officer and works in conjunction with the DDS. It shows the RD trains, orients new clinical diet aides and provides ongoing education for the clinical dietary aides. The job description does not outline all of the areas that the RD is responsible for under Title 22.

A 043 | 482.12 GOVERNING BODY
| A 043 |
There must be an effective governing body that is legally responsible for the conduct of the hospital. 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, record and document review, the hospital failed to effectively govern the activities and conduct of the hospital's operation in order to provide safe and quality health care in accordance with the Governing Body Bylaws, as evidenced by:

1. The failure to ensure an effective Quality Assurance and Performance Improvement (QAPI) program with oversight of the entire hospital operations in order to protect the safety of the hospital's patients. (refer to A-0263)

2. The failure to ensure a pharmaceutical service which promotes all aspects of a safe and effective medication program in order to meet the therapeutic needs of the hospital's patients. (refer to A-0490)

3. The failure to ensure a safe and effective food and dietary services in order to meet the nutritional needs of needs of the hospital's patients. (refer to A-0618)

4. The failure to provide a sanitary environment for the hospital's patients and to establish an active oversight program for the prevention, control and investigation of infections for the
| A 043 | Continued From page 4  
entire hospital operations. (refer to A-0747) |
|-------|---------------------------------------------------------------------|
| A 132 | 5. The failure to provide a physical environment to ensure the safety and well-being of the hospital's patients. (refer to A-0700) 
482.13(b)(3) PATIENT RIGHTS: INFORMED DECISION  
The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).  
This STANDARD is not met as evidenced by: Based on interview and record review, the hospital failed to follow their policy and procedure for Advanced Directives (a written plan for medical care when a patient is unable to speak for themselves) for two (Patient 19 and 20) of 33 sampled patients. 
This failure had the potential to deny patients the right to participate in their medical healthcare decisions.  
Findings:  
A review of facility policy and procedure titled, "Advanced Directives," dated 3/9/16, indicated in part, "A patient will be informed of their right to formulate and execute an advanced directive. A notice of the organization's advanced directive should be provided at the time an individual is admitted as an inpatient. The notice should be presented at the time of registration. Upon
Continued From page 5
request, the patient will be provided with information on how to formulate and execute an advance directive. Assistance will be provided to patients to complete an advance directive if requested."

During a concurrent observation and interview with Patient 20, on 2/8/17, at 8:30 a.m., Patient 20 was noted to be in her bed on her back with head of bed elevated, family friend at bedside. Patient 20 exhibited good eye contact, speech was within normal limits, affect appropriate to mood. Patient 20 described preadmission process and in-patient registration process, did not recall any information about Advanced Directives being shared with her.

During a concurrent record review and interview with Director of Business Office (Adm 1) on 2/8/17, at 9:30 a.m., while reviewing registration records of Patient 20, Adm 1 acknowledged that Patient 20 did not receive information about advanced directives, ADM 1 stated,"Because she (Patient 20 ) did not have a advanced directive she should have received information from the staff, this is a error."

During a concurrent record review and interview with ADM 1 on 2/8/17, at 11:30 a.m., while reviewing registration records of Patient 19, Adm 1 acknowledged that Patient 19 did not receive information about advanced directives, ADM 1 stated,"I don't know what happened here, this process has been trained and trained, they (staff) know what should occur this is another error."

482.13(c) PATIENT RIGHTS: PRIVACY AND SAFETY

A 142
### A 142 Continued From page 6

**Patient Rights: Privacy and Safety**

This STANDARD is not met as evidenced by:

Based on observation, interview, and medical record review, the hospital failed to ensure patient information was secured from unauthorized access. In the nuclear (radioactive) imaging room an unattended computer was displaying a patient's name and diagnosis.

This failure resulted in the potential for the unauthorized distribution of patient information.

**Findings:**

During a concurrent tour, interview, and medical record review, on 2/6/17 at 3:45 p.m., Director of Radiology (Rd 1) identified the unoccupied nuclear imaging room. Inspection of the room showed a computer terminal. Inspection of computer display "805737INF1" showed Patient 33's diagnosis of "GI Bleed" was displayed on the screen. Rd 1 acknowledged the screen showed the patient information described above.

Pharmacist (Pharm 1) stated it was not best practice for patient information to be displayed on an unattended computer terminal.

During an administrative record review, of the hospital's policy and procedure for Information Secure Policy (Revision Date August 25, 2016) showed, 2 Employee Responsibilities, 2.1 Employee Requirements, Unattended Patient Care Computers-"Unattended computers should be locked by the user when leaving the work area. This requirement is discussed with all employees during orientation. LVMC policy states that all Patient Care computers will have the
**Summary Statement of Deficiencies**

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### A 142
Continued From page 7

Automatic screen lock function to automatically activate upon 5 minutes of inactivity. Employees are not allowed to take any action which would override this setting.

### A 194

482.13(f) PATIENT RIGHTS: RESTRAINT OR SECLUSION

Restraint or Seclusion: Staff Training Requirements. The patient has the right to safe implementation of restraint or seclusion by trained staff.

This STANDARD is not met as evidenced by: Based on interview, observation, review of policy and procedures and review of documents, the facility failed to show evidence that staff were providing training to apply and remove leather restraints were qualified to do so.

This failure has the potential to place patients, staff, and visitors at risk.

Findings:

The facility policy and procedure titled “Restraint or Seclusion; Use of ” revised date 5/16, indicated “...m. 6) Restraint devices are to be applied/removed only by staff authorized, trained, and with the demonstrated competency to do so...6.e. Staff who provide Training and Competency Assessment of Other Staff. Individuals providing the training and competency assessments noted in this policy must be qualified as evidenced by education, training, and experience in techniques used to address patients behaviors for the populations being served. Trainers should demonstrate a high level of knowledge this policy, as well as state and...
A 194 Continued From page 8

federal law, and CMS accreditation standards."

During an interview with licensed nurse 9 (LN 9),
on 2/9/17, at 10:25 a.m., she stated that the
annual restraint teaching is rotated and this year
physical therapist 1 (PT 1) was at the restraint
table. The restraints taught with a return hands
on demonstration were "soft restraints."

During an interview with administrative staff 2
(AS 2), on 2/9/17, at 9:20 a.m., AS 2 stated that
he does not train staff in restraining patients. He
teaches "CPI" (Crisis Prevention Institute) "just
the escalation curve and self defense."

During an interview with LN 6, on 2/9/17, at 4
p.m., she stated that they use leather restrains in
the emergency department (ED) and staff go
through annual training during skills week that
includes restraints. This year a physical therapist,
PT 1, was the instructor. When asked about the
training the PT 1 had she said she "couldn't
speak to his training." LN 6 pulled down a box of
hard leather restrains and stated that these were
used, when necessary, in the ED. She also
indicated that there were no manufacturers
instructions on how to apply and remove the
leather restrains.

During an interview with registered nurse 8 (RN
8), on 2/9/17, at 4:30 p.m. RN 8 said there was
training on applying leather restrains but was not
sure what gives the trainer the ability to instruct.

During an interview with RN 9, on 2/9/17, at 4:35
p.m., RN 9 explained they teach restraints at the
annual skills fair. The department directors are
more trained but not sure what additional training
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<td>A 194</td>
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<td>Continued From page 9 is needed to be able to sign off restraint training. RN 9 received some restraint training on-line. RN 9 was not sure how someone becomes a preceptor to sign off competency on restraints. During an interview with RN 10, on 2/9/17, at 4:45 p.m. RN 10 indicated that a preceptor gave instructions on using leather restraints but was not sure what qualifications are needed to be a preceptor. Did some on-line education regarding restraints as well and during the annual skills fair they taught &quot;soft ties&quot; but no leather. During an interview with LN 7 and LN 11 on 2/10/17, at 10:25 a.m., they both agreed there was no one on staff trained to demonstrate the application of leather restraints. LN 7 said they also use additional on-line sources, such as, a training module from the &quot;Center for Improvement in Healthcare Quality&quot; (CIHQ) titled &quot;Restraint and Seclusion&quot; 2013 which indicated for restraint application &quot;Restraint devices are to be applied/removed in accordance with manufacturers instructions and used in a manner consistent with their intended use.&quot; LN 7 also said that she had not looked at the leather restraints in the ED and was not aware of any manufacturers instructions for the use of leather restraints.</td>
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<td>A 263</td>
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<td>482.21 QAPI</td>
<td>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</td>
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### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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| 02/10/2017                | A 263              | Continued From page 10 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 document review, the hospital failed to ensure an effective, hospital-wide Quality Assurance and Performance Improvement (QAPI) as evidence by:

1. The failure to provide QAPI integration and oversight to the all aspects of the food and dietary services. (refer to A-0618)
2. The failure to provide QAPI integration and oversight to all aspects of the pharmaceutical services. (refer to A-0490)
3. The failure to provide QAPI integration and oversight to all aspects of the infection control program. (refer to A-0747)
4. The failure to provide QAPI integration and oversight to all aspects of the hospital's physical environment. (refer to A-0700)

The cumulative effects of these systemic problems resulted in QAPI inability to provide care and services in a safe and effective manner in accordance with the statutorily-mandated Conditions of Participation for QAPI. 482.21(a), (b)(1),(b)(2)(i), (b)(3) DATA COLLECTION & ANALYSIS | A 263 | | |

<p>| A 273 | | DATA COLLECTION &amp; ANALYSIS | A 273 | | | |</p>
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(a) Program Scope
(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes ...
(2) The hospital must measure, analyze, and track quality indicators ... and other aspects of performance that assess processes of care, hospital service and operations.

(b) Program Data
(1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.
(2) The hospital must use the data collected to--
   (i) Monitor the effectiveness and safety of services and quality of care; and ....
(3) The frequency and detail of data collection must be specified by the hospital's governing body.

This STANDARD is not met as evidenced by:
Based on Administrative Staff interview and document review, the hospital failed to ensure:

1) an effective performance improvement program for food and nutrition services which accurately reflected the depth and scope of departmental operations. The hospital failed to ensure there was measurable data and benchmarks on the departmental indicators and
A 273 Continued From page 12

to comprehensively incorporate departmental operations into the hospital wide performance improvement program. Failure to develop a comprehensive program that identified opportunities for improvement may result in compromised outcomes, for a licensed bed count of 60, in relationship to medical and nutritional status;

2) the consistent analysis of collected quality (quality indicator) data. The pharmacy's sterile (germ free) intravenous (IV, directly into a vein) compounding (mixing) area was tested for viable (living) airborne microorganisms twice in the past year. Both tests came back positive for microorganisms. The test results were not sent to the hospital's infection preventionist for identification of potential pathogens in the hospital's patient population. The test results were not sent to the hospital's pharmacy and therapeutics committee. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>.

Findings:

1. During food production observations on 2/7-2/9/17 deficient practices were noted in the areas of departmental staff competency, safe food handling, provision of meals in accordance with physician ordered diets and a lack of a well-defined disaster feeding plan that met patient nutritional parameters in accordance with standards of practice (Cross Reference A23, A620, A622, A630, A701 and A749).
A 273 Continued From page 13

On 2/8/17 at 12:45 p.m., an interview was conducted with the Director of Dietary Services (DDS) regarding the Quality Assurance Performance Improvement (QAPI) plan for his department. The DDS stated they are doing test trays and keep a log when done and these are done mostly by the diet aids and trayline observations. He stated he puts in report and their goal is 100% and they have been doing well. The DDS was not able to show what data he reported to the Board at this time but it would be provided.

On 2/9/17 at 9:50 a.m., an interview was conducted with a Registered Dietician (RD 5) regarding clinical nutrition QAPI. RD 5 stated they have not been monitoring, collecting or reporting anything for clinical nutrition.

The DDS provided the departments’ quality improvement (QI) tracking documents. Review of the document titled “Dietary Annual Report to the Board of Directors” dated July 2016, showed the QI activities were: Dietitians continue to perform random "tray-line check" on patient nutrition/meal; Diet aides continue performing random test tray evaluations three times per week to check on temperatures, food presentation and taste; the distribution of patient nutritional snacks continues to be monitored; meeting with other dietary directors from the other facilities in their community to review all issues pertaining to our departments in order to maintain similar criteria concerning purchasing, staffing and department policies; and random rounding checks on patients in all departments on their dietary needs. There was no activities regarding clinical nutrition.  There was no metric.
A 273 Continued From page 14

In an interview, on 2/9/17 at 8:53 a.m., with the Quality Improvement (LN 1), she described the hospitals' quality assessment performance improvement reporting structure. She stated that each department was responsible for providing performance improvement activities. When reviewing the Dietary Annual Report, LN 1 stated she has not seen any metrics or data or measurable benchmarks from the food and nutrition department. LN 1 stated this was lacking and this had came up in the last CIHQ survey. LN 1 stated all directors from the different departments meet monthly to discuss team progress and goals at the Guidance Committee. When asked how quality helps the directors be able to self-identify areas for improvement, LN 1 stated they have a risk assessment online that the directors have access to but it was new and a new focus and this had not been done yet with the DDS.

The above interview with LN 1 also revealed it was hospitals' expectation that Department managers, in conjunction with the Quality Department, develop meaningful performance improvement audits. LN 1 acknowledged that based on the submitted QI activities it was likely the department required additional assistance and accountability in developing and implementing a program that demonstrated measurable improvement. Developing, performing and evaluating of continuous quality improvement program was within the scope of the Registered Dietitian position description and Performance Improvement Activities was under...
Review of the hospital's Quality Assurance Integrated Process Improvement Program revised 5/16, showed their approach included development, monitoring via data collection, evaluation of current processes, and improving and sustaining improved performance. It showed the Integrated QI Plan structure was an organization-wide plan and it applied to all departments, care, treatment, and service settings.

2. During a concurrent interview and record review, on 2/7/17 at 3:30 p.m., Pharmacist (Pharm 1) identified the May 2016 Pharmacy Services Semi-Annual Report to the Pharmacy & Therapeutics Committee and the November 2016 Pharmacy Services Annual Report to the Pharmacy & Therapeutics Committee. Inspection of the reports did not show quality measures from the sterile IV compounding program were reported to the Pharmacy & Therapeutics Committee. Pharm 1 reviewed the reports and acknowledged the two reports did not document quality measures were reported to the P & T committee. Continuing the interview, Pharm 1 identified the Clean Air Certification, Viable Air and Surface Environmental Report, dated June 28, 2016 and December 21, 2016. Inspection of the reports showed Bacillus sp (microorganism) and Staphlococcus coagulase (-) (microorganism) grew from the air sample taken on December 21 and staphylococcus coagulase (-) (microorganism), Bacillus sp (microorganism), and Micrococcus sp (microorganism), grew from the air sample taken on June 28. Pharm 1 was asked to describe the process for reviewing the
### Statement of Deficiencies and Plan of Correction

**Provider/Supplier/CLIA Identification Number:** 050110

**Name of Provider or Supplier:** Lompoc Valley Medical Center

**Street Address, City, State, Zip Code:** 1515 E Ocean Avenue, Lompoc, CA 93436

**Date Survey Completed:** 02/10/2017

**Summary Statement of Deficiencies**

**ID Prefix Tag**

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<td>Continued From page 16 results of the two tests. His description did not include that the hospital’s infection control professional, or the P &amp; T committee, reviewed the results. Pharm 1 stated the pharmacy did not forward the results outside of the department.</td>
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During a concurrent interview and record review, on 2/8/17 at 11:30 a.m., Infection Control Preventionist (ICP) identified the Clean Air Certification, Viable Air and Surface Environmental Report, dated June 28, 2016 and December 21, 2016. Review of the reports showed Bacillus sp and Staphlococcus coagulase (-) grew from the air sample taken on December 21 and staphylococcus coagulase (-), Bacillus sp, and Micrococcus sp, grew from the air sample taken on June 28. ICP reviewed the reports and acknowledged the above. ICP was asked if the organisms identified above, contaminated compounded sterile preparations prepared in the pharmacy, could have been a potential pathogen in the hospital's patient population. ICP stated the organisms identified could have been a potential pathogen in the hospital's patient population. ICP stated, that in her role as the hospital's infection control professional, it was her expectation the results of the above tests should have been sent to her and the infection control committee.

During a concurrent interview and record review, on 2/9/17 at 9:40 a.m., Registered Nurse (LN 1) and Pharm 1 identified a document showing 3296 IVs were compounded in the pharmacy from 2/8/16 to 2/7/17. LN 1 was asked for the number of patients admitted to the hospital over the past year. LN 1 stated approximately 5000 patients were admitted in the last year.
### A 273 Continued From page 17

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, General "The intent of this document is to prevent harm to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins...in compounded sterile preparations (CSPs)." Further review showed, Environmental quality and Control, Environmental Monitoring & Maintenance...6. Any CFU counts above action levels or any potential pathogens regardless of CFU shall be remedied immediately with a deep clean of the environment, review of adequacy of cleaning procedures, operational procedures, and air filtration efficiency in consultation with the infection preventionist for the positive environments. Re-sampling shall be performed to determine if any changes made have provided resolution to the positive tests."

The United States Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the quality, purity, identity, and strength of medicines. USP's drug standards are enforceable in the United States by the Food and Drug Administration and are published in the United States Pharmacopeia/National Formulary (USP 35/NF 30). The USP revised general chapter <797> entitled PHARMACEUTICAL COMPOUNDING (mixed)-STERILE (germ free) PREPARATIONS (CSP) documents in the Introduction that "The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial toxins..." [Adherence to these practice and quality
### Summary Statement of Deficiencies

**A 273 Continued From page 18**

Standards allows the hospital to assign beyond use dates (date beyond which a CSP cannot be started) to CSPs as described in USP <797>.

An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 60) showed, Action Levels, Documentation, and Data Evaluation, "The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted...Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered as each sampling location and trended over time. The numbers in Table 4 should be used only as guidelines. Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as cfu using an impact air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or..."
**A 273 Continued From page 19**

industrial hygienist."

A 396 482.23(b)(4) NURSING CARE PLAN

The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.

This STANDARD is not met as evidenced by:

Based on interview and record review, the hospital failed to ensure the nursing care plan was initiated for one of 33 sampled patients (Patient 20) which has the potential to result in lack of continuity of care and failure to meet patient care needs.

Findings:

During concurrent record review and interview with a licensed nurse (LN 4) on 2/8/17, at 8:30 a.m., record revealed that Patient 20 was admitted to the labor and delivery service of the hospital on 2/6/17, at 1:33 a.m. Further record review indicated Patient 20 initial nursing assessment took place on 2/6/17, at 8 a.m., and initial care plan occurred on 2/6/17, at 9:45 a.m. LN 4 was asked what the hospital policy was for timing of assessment and care plans, LN 4 stated, "They are to be initiated within 12 hours of admission."

Review of hospital policy and procedure titled, "Assessment and Reassessment of Patients Nursing Practice Standards," dated 11/91, revised 01/14, indicated in part,..."Each department has a standard time frame for the initial assessment and for reassessment periods according to the level of care provided and the
A 396 Continued From page 20
patient population of that unit." Further review of
the clinical assessment guidelines for the labor
and delivery department indicated initial
assessment was to occur, "Within 15 minutes" of
admission.

A 405 482.23(c)(1), (c)(1)(i) & (c)(2) ADMINISTRATION
OF DRUGS

(1) Drugs and biologicals must be prepared and
administered in accordance with Federal and
State laws, the orders of the practitioner or
practitioners responsible for the patient's care as
specified under §482.12(c), and accepted
standards of practice.

(i) Drugs and biologicals may be prepared and
administered on the orders of other practitioners
not specified under §482.12(c) only if such
practitioners are acting in accordance with State
law, including scope of practice laws, hospital
policies, and medical staff bylaws, rules, and
regulations.

(2) All drugs and biologicals must be
administered by, or under supervision of, nursing
or other personnel in accordance with Federal
and State laws and regulations, including
applicable licensing requirements, and in
accordance with the approved medical staff
policies and procedures.

This STANDARD is not met as evidenced by:
Based on interview, record review, and review of
the facility's policy and procedures, the facility
failed to:

1. Reassess patient's pain medication for four of
### Statement of Deficiencies and Plan of Correction

#### Provider/Supplier/CLIA Identification Number:
- Provider’s Identification Number: 050110

#### Multiple Construction
- Wing B

#### Date Survey Completed:
- 02/10/2017

#### Name of Provider or Supplier:
- Lompoc Valley Medical Center

#### Street Address, City, State, Zip Code:
- 1515 E Ocean Avenue, Lompoc, CA 93436

#### Summary Statement of Deficiencies

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33 patients (Patients 6, 10, 15, and 19) in accordance with acceptable standards of care and the facility's policy and procedure. This failure had the potential to provide inadequate pain control for patients.

2. Ensure physicians’ orders for patient controlled analgesia (pain control) (PCA) were followed. In two out of two charts reviewed (Patients 27 and 28), the hospital did not document all of the ordered monitoring parameters (level of sedation (wakefulness) or pain level). These failures resulted in the potential for patients to be exposed to excessive sedation or a delay in receiving pain relief.

3. Ensure physicians’ orders for insulin (lowers blood glucose (sugar) infusion were followed. In one out of two charts reviewed (Patient 31), the hospital did not document it contacted a physician for a situation not adequately addressed by the order. This failure resulted in the potential for patients to experience a delay in reaching goal (normal) blood glucose.

4. Ensure nurses met all the USP<797> requirements for compounding (mixing) immediate use sterile (germ free) preparations. In the intensive care unit and the emergency department, nurses compounded intravenous (IV, directly into a vein) insulin (lowers blood glucose (sugar) infusions. The hospital did not have a process to ensure all the USP<797> requirements for immediate use compounding were followed. These failures resulted in the potential for the hospital's patients to be exposed to 15 IV insulin medications that were not compounded following all USP<797>
### Summary Statement of Deficiencies

(A 405 Continued From page 22)

**5.** Ensure medication syringes in the computerized tomography (CT, X-ray study) room were labeled. Technicians in the CT room prepared syringes of normal saline (salt water) and contrast (improves CT picture). The syringes were not labeled as required by the hospital's policy and procedure and USP<797>. These failures resulted in the potential for patients to be exposed to preventable medication errors.

**6.** Ensure that medications were administered and documented in accordance with the Physician's order and the hospital's policy and procedures for one of 33 patients (Patient 32). These failures had the potential to provide inadequate pain control for the patient.

**Findings:**

The facility policy and procedure titled "Pain Management" date revised 8/16, indicated "...2. Policy: Patients have the right to pain management. It is the policy of [hospital name] to do the following: a. Assessment/Reassessment. Conduct an appropriate assessment and/or reassessment of a patient's pain consistent with the scope of care, treatment, and service provided in the specific care setting in which the patient is being managed... c. Response to care. Assess the patient's response to care, treatment, and service implemented to address pain...4. Reassessment Following Treatment for Pain. If a treatment intervention for pain is provided, the response to that intervention should be reassessed. Reassessment is recommended to occur within 60 minutes following treatment.
A 405 Continued From page 23
(depending on the type of intervention..."

1. During a concurrent record review of Patient 6's clinical record and interview with a licensed nurse (LN 8), on 2/7/17, at 10 a.m., record revealed that on 1/31/17, at 8:48 p.m., Patient 6's doctor ordered morphine (a narcotic to treat moderate to severe pain) injectable 3 milligrams intravenously (administered into a vein) every 2 hours PRN (use when necessary) for severe pain level of 8-10. Further record review indicated Patient 6 received PRN morphine on 02/01/17, at 6 p.m., for complaints of severe pain, record did not reveal reassessment of pain after medication was administered. LN 8 acknowledged lack of documented reassessment, stating, "Yes, I see this is missing."

During a concurrent record review of Patient 19's clinical record and interview with LN 5, on 2/8/17, at 10:45 a.m., record revealed that on 2/7/17, at 12 a.m., Patient 19's doctor ordered hydromorphone (a narcotic to treat moderate to severe pain) .4 milligrams intravenous every 10 minutes PRN for pain level of 5-7. Further record review revealed Patient 19 received hydromorphone on 2/7/17, at 12:14 p.m., on 2/7/17, at 12:29 p.m., and on 2/7/17, at 12:49 p.m., Patient 19's record did not reveal any pre-pain medication assessment of pain or post medication administration assessment of pain. LN 5 acknowledged lack of documented assessment's stating, "It should have been documented, the pain levels, I will have to talk with the staff."

During a review of Patient 10’s clinical record on 2/9/17 at 10 a.m. with LN 6 and LN 11, the medication administration record (MAR) indicated
A 405 Continued From page 24
the patient had received morphine (an opioid pain medication used to treat moderate to severe pain) 2 mg. (milligrams) intravenous (medication administered directly in to venous circulation) push on 2/5/17 as a one time order. The medication was administered at 9:47 p.m. The reassessment to determine the effectiveness of the medication was documented as being done at 11:36 p.m., an hour and forty-five minutes after the medication was administered. Both LN 6 and LN 11 agreed that the reassessment had taken place more than an hour after the medication had been administered.

During a review of Patient 15’s clinical record on 2/9/17 at 10 a.m. with LN 6 and LN 11, the MAR indicated Patient 15 had received morphine 5 mg. intravenous push every two hours PRN for moderate pain (4-7). The medication was administered on 2/3/17 at 5:34 p.m. There was no documentation of a reassessment to determine the effectiveness of the medication being done. Both LN 6 and LN 11 agreed there was no documentation that a reassessment of the PRN medication had ever taken place.

2. During a concurrent interview and medical record review, on 2/8/17 at 12:10 p.m. Registered Nurse (LN 16) and Registered Nurse (LN 15) identified Patient 27’s electronic medical record (EMR, computer medical record). Review of the EMR showed Patient 27 was admitted to the hospital on 8/30/16. Further review showed a physician's order, dated 8/30/16 at 13:01 for HYDROMorphone (narcotic pain reliever) PCA. The PCA order included for the nurse to monitor the level of sedation "every 30 minutes after first dose X 2, every 1 hour X 2, every 2 hours X 2,
A 405

Continued From page 25
every 4 hours thereafter until PCA is discontinued." Review of the medication administration record showed the PCA was started on 8/30/16 at 1556. Review of the Vital Signs Measurement, on 8/30/16 from 1556 to 1939, showed the first documented level of sedation was at 1939 (3.5 hours after the PCA was started). LN 16 and LN 15 reviewed the EMR and acknowledged the level of sedation was not documented as ordered by the physician.

During a concurrent interview and medical record review, on 2/8/17 at 12:40 p.m., LN 16 and LN 15 identified Patient 28’s EMR. Review of the EMR showed Patient 28 was admitted to the hospital on 8/2/16. Further review showed a physician's order, dated 8/2/17 for HYDROmorphine PCA. The PCA order included for the nurse to monitor the pain level "every 30 minutes after first dose X 2, every 1 hour X 2, every 2 hours X 2, every 4 hours thereafter until PCA is discontinued." Review of the medication administration record showed the PCA was started on 8/2/16 at 1117. Further review showed pain levels were documented on 8/2/16 at 1220, 1400 and 1600. LN 16 and LN 15 reviewed the EMR and acknowledged the pain levels were not documented as ordered by the physician.

An administrative record review, of the hospital's policy and procedure for Patient Controlled Analgesia (PCA) (Date Revised: 11/16) showed, 2. Procedure, i. "Initiation of the PCA requires close observation from nursing staff. Vital signs will be assessed and documented as follows: every 1 hour for 4 hours, every 2 hours for 12 hours and then every 4 hours until
### SUMMARY STATEMENT OF DEFICIENCIES

**Deficiency:** A 405

**Description:**

- Discontinuation of PCA. The patient should be closely monitored for: 1) Pain level prior to PCA medication and during administration of narcotics, 2) Level of sedation...

**Additional Details:**

- During a concurrent interview and medical record review, on 2/9/17 at 10:35 a.m., Registered Nurse (LN 15) identified Patient 31's electronic medical record (EMR, computer medical record). Review of the EMR showed Patient 31 was admitted to the hospital on 10/6/16. Further review showed a physician's order, dated 10/7/16 at 1643 for CCU Glycemic (sugar) Control Protocol (insulin drip for control of blood sugar) "Target Blood Glucose (BG) Levels: 140-180 mg (milligram)/dL (deciliter)...If BG>=500 mg/dL, a physician should be consulted for specific orders. Also, notify a physician if the response to the insulin infusion is unusual or unexpected, or if any situation arises that is not adequately addressed by these guidelines."

- Review of the medication administration record showed the insulin infusion was not started on 10/7/16. Review of the EMR showed the following BG results: 10/7/17 at 1700 BG 102 (below target), 1800 BD 112 (below target), 2000 BG 148 (in target), and 2100 BG 217 (greater than target). Review of the EMR did not show nursing contacted a physician for the BG results listed above. LN 15 reviewed the EMR and acknowledged, based on the glycemic control protocol order, the nurse should have contacted the physician for clarification of the order.

- During a concurrent tour, interview, and record review, on 2/7/17 at 1:25 p.m., in the intensive care unit (ICU), Registered Nurse (LN 15) identified the medication refrigerator. Inspection
A 405 Continued From page 27

of the refrigerator showed a multidose (MDV, contained more than one dose of medication) bottle of 100 units/ml (milliliter) 3 ml regular insulin. LN 15 was requested to describe how the insulin was used when a nurse prepared a continuous infusion bag of insulin (100 units / 1 ml added to a 100 ml bag of IV fluid). LN 15’s description included that a MDV of insulin was used for up to 28 days, or when empty, whichever came first. LN 15’s description showed that a single bottle of insulin could have been used to make up to 3 insulin infusions.

During an interview, on 2/8/17 at 9:35 a.m., the Pharmacist (Pharm 1) acknowledged the ICU nurses compounded IV insulin infusions when the pharmacy was closed. He also stated the emergency department compounded IV insulin using the same MDV insulin dating process. Pharm 1 was asked if the reuse of a MDV insulin vial meets the USP<797> immediate use provision. Pharm 1 acknowledged if the vial was punctured more than twice the process would not meet USP’s immediate use provision.

During a concurrent interview and record review, on 2/9/17 at 9:40 a.m., Pharm 1 identified the document showing, for the past year, 15 insulin IV’s were compounded by the nurses outside of the pharmacy. Registered Nurse (LN 1) was asked for the number of patients admitted to the hospital over the past year. LN 1 stated approximately 5000 patients were admitted in the last year.

An administrative record review, of the hospital’s policy and procedure for IV Push (fast administration), IV Piggyback, IV Drip
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Medications (Date Revised: 6/24/2016) showed, 2. Policy., h. "Pharmacy Services will prepare all large volume solutions during pharmacy working hours unless the delay required to complete the IV would cause the patient harm. After pharmacy working hours, the nurse shall make any needed medications not already prepared by pharmacy immediately before use in the designated IV prep area using proper aseptic (sterile) technique."

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, Storage & Beyond-Use (expiration) Dating, 7. "For Immediate Use CSPs (compounded sterile preparations) prepared outside the hood in urgent situations...b. Immediate use CSPs shall be limited to simple transfer of not more than three commercially manufactured sterile nonhazardous products from the manufacturer's original containers and not more than two entries into any one container or package (e.g. bag, vial) of sterile infusion solution or administration container/device."

The United States Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the quality, purity, identity, and strength of medicines. USP's drug standards are enforceable in the United States by the Food and Drug Administration and are published in the United States Pharmacopeia/National Formulary (USP 35/NF 30). The USP revised general chapter <797> entitled PHARMACEUTICAL COMPOUNDING (mixed)-STERILE (germ free) PREPARATIONS (CSP) documents in the Introduction that "The objective of this chapter is to describe conditions and practices to prevent..."
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:
050110

(X2) MULTIPLE CONSTRUCTION
A. BUILDING _____________________________
B. WING _____________________________

(X3) DATE SURVEY COMPLETED
02/10/2017

NAME OF PROVIDER OR SUPPLIER
LOMPOC VALLEY MEDICAL CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
1515 E OCEAN AVENUE
LOMPOC, CA 93436

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**SUMMARY STATEMENT OF DEFICIENCIES**
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

A 405 Continued From page 29

harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial toxins...

[Adherence to these practice and quality standards allows the hospital to assign beyond use dates (date beyond which a CSP cannot be started) to CSPs as described in USP <797>.

An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 45-46) showed, Immediate-Use CSPs, "The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP....Preparations that are medium-risk level and high-risk level (of microorganism contamination) CSPs shall not be prepared as immediate-use CSPs...Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into an one container or package (e.g., bag, vial) of sterile infusion solutions or administration container/device...."

5. During a concurrent tour, interview, and record review, on 2/6/17 at 4 p.m. in the CT room, the 2 channel syringe injector was identified. Inspection of the injector showed two syringes attached to the injector. IV (intravenous, directly into a vein) tubing was attached to each of the syringes. Inspection of the syringes showed...
A 405

Continued From page 30

Handwriting on each of the syringes. One was labeled NaCl and the other was labeled contrast. A patient was not in the CT room. Pharmacist (Pharm 1) was asked if the two medication syringes were labeled as required by the hospital's policy and procedure. Pharm 1 inspected the two syringes and stated they were not labeled as required by the hospital's policy and procedure.

During an administrative record review, of the hospital's policy and procedure for Administration of Medications (Date Revised: 8/16) showed, 4. Procedure, 3) "The Correct Dose. To ensure that the dosage of the medication matches prescribed dose and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or low)...6) IV admixtures for Immediate Use only. Immediate use only shall be labeled with the following: a) Patient identification information., b) The names and amounts of all ingredients., c) The name or initials of the person who prepared it., d) The exact one hour "Beyond use date" (BUD)."

The United States Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the quality, purity, identity, and strength of medicines. USP's drug standards are enforceable in the United States by the Food and Drug Administration and are published in the United States Pharmacopeia/National Formulary (USP 35/NF 30). The USP revised general chapter <797> entitled PHARMACEUTICAL COMPOUNDING (mixed)-STERILE (germ free) PREPARATIONS (CSP) documents in the Introduction that "The objective of this chapter is to describe conditions and practices to prevent
## Summary Statement of Deficiencies

### A 405

Continued From page 31

Harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial toxins...

[Adherence to these practice and quality standards allows the hospital to assign beyond use dates (date beyond which a CSP cannot be started) to CSPs as described in USP <797>.

An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 45-46) showed, Immediate-Use CSPs, "The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP....Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs...Immediate-use CSPs are exempt from the requirements described for Low-Risk Level CSPs only when all of the following criteria are met: 1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into an one container or package (e.g., bag, vial) of sterile infusion solutions or administration container/device....5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time."
A 405

Continued From page 32

6. Review of the clinical record for Patient 32 on 2/9/17 at 11:15 a.m. revealed that this patient's physician had written the following medication order on 1/13/17 at 3:49 p.m.: "Tylenol 650 milligrams (mg) by mouth every 6 hours as needed for mild pain (1-3) or Temperature greater than 100.4 ...". Further review of Patient 32's clinical record revealed that on 1/14/17 at 4 p.m., this patient had been given one dose of Tylenol 650 mg. There was no documentation in the patient's clinical record to indicate whether this Tylenol had been given to this patient for "mild pain" or whether this medication had been given to the patient for an elevated temperature. Interview with the Med-Surg Nurse Manager on 2/9/17 at 11:20 a.m. revealed that she could not locate anywhere in the patient's clinical record, why this Tylenol had been administered to Patient 32. Further interview with the Med-Surg Nurse Manager revealed that the hospital did not have a universal location for the hospital staff to document these indications. The Med-Surg Nurse Manager indicated that one of the two indications for administering this medication should have been documented on either the patient's Medication Administration Record (MAR), on the patient's flow sheet, or in the Nurse's progress notes.

Review of the clinical record for Patient 32 on 2/9/17 at 12:20 p.m. revealed that this patient's physician had written the following medication order on 1/16/17 at 1:27 p.m.: "Acetaminophen-Hydrocodone 325/5 milligrams (mg) one tablet by mouth every 4 hours as needed for moderate pain (4-7)." One dose of the Acetaminophen-Hydrocodone had been administered to Patient 32 on 1/17/17 at 8:04
### Statement of Deficiencies and Plan of Correction

**Provider/Supplier/CLIA Identification Number:** 050110  
**State:** CA  
**Location:** Lompoc Valley Medical Center  
**Address:** 1515 E Ocean Avenue, Lompoc, CA 93436  
**Survey Date Completed:** 02/10/2017

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Review of the patient's Medication Administration Record (MAR), Nurse's progress notes, and the hospital's flow sheet for this patient failed to provide evidence that a reassessment of the patient's pain had been completed as outlined in the hospital's policy and procedure. No intensity had been documented for the reassessment of the Acetaminophen-Hydrocodone dose which had been administered to Patient 32 at 8:04 a.m. on 1/17/17. Review of the hospital's policy and procedure entitled: "Pain Management", dated 8/16, stated: "...Routine Reassessment. Inpatients will be reassessed for the presence of pain no less frequently than the minimum requirements ... At a minimum, this reassessment shall consist of noting the intensity of the patient's pain." |
| A 438 | 482.24(b) FORM AND RETENTION OF RECORDS  
The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.  
This STANDARD is not met as evidenced by:  
Based on interview and record review, the facility failed to accurately document one medical record (Patient 6) of 33 patients sampled.  
This failure has the potential for patients to experience a lack of continuity of care between providers due to inaccurate information. |
### Findings:

During a concurrent record review of Patient 6’s clinical record and interview with a licensed nurse (LN 12), on 2/7/17, at 10 a.m., record revealed that on 1/25/17, at 11:30 p.m., a telephone order from Patient 6’s doctor for lorazepam (a sedative medication to treat seizures and anxiety) 1 milligram intravenous every 4 hours PRN (use when necessary) for seizures (a disorder in which nerve cell activity in the brain is disturbed). This order was discontinued on 1/30/17 at 11:59 p.m. Further nursing progress note record review revealed Patient 6 on 2/1/17, at 12:11 a.m., indicated, "... Patient called and said she was having a panic attack, went to room and found patient in bed on her right side; she stated that her heart was pounding really bad...She told me she sometimes has panic attacks at home when she is asleep and wakes up short of breath..." Review of medication administration record for Patient 6, indicated Patient 6 received lorazepam 1 milligram on 1/31/17 at 12 a.m. LN 12 acknowledged that Patient 6 nursing notes did not describe a seizure and that medication (lorazepam) was administered after discontinued date, LN 12 stated, "No, what she was having was not a seizure and I am not sure why it (lorazepam medication) was given after the discontinuation date."

### A 490 482.25 PHARMACEUTICAL SERVICES

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff
Continued From page 35

is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

This CONDITION is not met as evidenced by:

Based on observation, interview, and administrative record review, the hospital failed to ensure the provision of pharmaceutical services and care that meets the needs of the patients as evidenced by:

1. The hospital failed to ensure the pharmacy's viable (living) airborne sample reports, from the sterile (germ free) intravenous (IV, directly into a vein) compounding (mixing) area, were sent to the infection preventionist for identification of potential pathogens (microorganisms causing disease) in the hospital's patient population. The pharmacy's sterile IV compounding area was tested for viable airborne microorganisms twice in the past year. Both tests came back positive for microorganisms. The test results were not sent to the hospital's infection preventionist for identification of potential pathogens in the hospital's patient population. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>. (See A-0501 #1)

2. The hospital failed to ensure the pharmacy's sterile (germ free) intravenous (IV, directly into a vein) compounding (mixing) area was free of dust, debris, and black sticky material. The ante-room (area to prepare for mixing IVs) and buffer room (area for mixing sterile IVs) contained...
## A 490 Continued From page 36

Dust and debris on flat surfaces and in plastic bins. The ante-room had black material stuck to the floor. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>. (See A-0501 #2)

3. The hospital failed to ensure the intravenous (IV, directly into a vein) compounding (mixing) hood (device to maintain sterile (germ free) work area) was cleaned with sterile alcohol and sterile water. The IV hood was cleaned with non-sterile alcohol and an opened bottle of water. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>. (See A-0501 #3)

4. The hospital failed to ensure the ceiling fixtures in the sterile (germ free) intravenous (IV, directly into a vein) compounding (mixing) area were sealed against the surface. In the ante-room (area to prepare for mixing IVs) and buffer room (area for mixing IVs) the gaps between the fixtures and the ceiling were not sealed. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>. (See A-0501 #4)

5. The hospital failed to ensure documented competency (ability to do a task successfully) of the staff that cleaned the sterile (germ free) intravenous (IV, directly into a vein) compounding (mixing) area. The EVS (environmental services)
A 490 Continued From page 37

A competency checklist did not include the specific duties required for cleaning of the sterile IV compounding areas. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>. (See A-0501 #5)

The cumulative effects of these systemic problems resulted in the pharmacy's inability to provide pharmaceutical services and care in a safe and effective manner in accordance with the statutorily-mandated Conditions of Participation for Pharmaceutical Services.

A 491 482.25(a) PHARMACY ADMINISTRATION

The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

This STANDARD is not met as evidenced by:

Based on observation, interview, and record review, the hospital failed to ensure California Code of Regulations for emergency drugs were followed. The hospital's emergency drug supplies, stocked in a crash cart, included medications that were not checked and sealed by a pharmacist. The hospital's crash cart drugs included medications that were not authorized to be stocked. The documentation of the first drug to expire was inaccurate. The list of medications inside the cart was not outside the cart.

These failures resulted in the potential for patients to experience a delay in receiving medications required in an emergency.

Findings:
During a concurrent tour, interview, and record review, on 2/7/17 at 9:50 a.m., in the medical surgical nursing unit, Registered Nurse (LN 17) identified an adult emergency cart. LN 17 was requested to identify the list posted outside of the cart, of the medications stocked inside. LN 17 was unable to find the requested listing of medications. LN 17 removed the nurse applied green plastic lock that secured the emergency cart. The pharmacy sealed medication drawer was labeled with the expiration date of the first drug to expire “6/1/17.” LN 17 was requested to identify the expiration date of the first drug to expire, that was located outside of the emergency cart. LN 17 identified the crash cart check list. The list showed the expiration date of the first drug to expire was “5/1/17.” Inspection of the pharmacy sealed mediation tray showed a vial of naloxone (used to reverse the effects of narcotics) 0.4 mg (milligram)/ml (milliliter) taped to the top of the medication tray (the naloxone was not in the pharmacy sealed medication tray). Continuing the emergency cart inspection showed intravenous (IV, directly into a vein) fluids in the bottom drawer (not sealed by pharmacy). The fluids included 1 liter (L) bags of normal saline (salt water) and lactated ringers (IV fluid), and 500 ml bags of normal saline and D5W (sugar water). Pharmacist (Pharm 1) inspected the cart and acknowledged the above observations.

During a concurrent tour, interview, and record review, on 2/7/17 at 12:45 p.m., in the intensive care unit (ICU), Registered Nurse (LN 15) identified an adult crash cart. Inspection of the pharmacy sealed mediation tray showed the
## Statement of Deficiencies and Plan of Correction

**Provider/Supplier/CLIA Identification Number:** 050110

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### Summary Statement of Deficiencies
(Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)

- **Expiration Date of the First Drug to Expire:**
  - **6/1/17.**
  - LN 15 identified the crash cart check list. Review of the list showed the expiration date of the first drug to expire was 3/17. LN 15 acknowledged the above observations.
  - Continuing the ICU inspection, LN 15 identified the Pediatric Box "Tote G." LN 15 stated the purpose of the pediatric box was to provide medications needed in an emergency until the pediatric emergency cart arrived. Inspection of the box showed that it was sealed by a nursing applied green seal. LN 15 acknowledged the box (including the medications inside) was not sealed by pharmacy.
  - An administrative record review, of the hospital’s Adult Crash Cart Inventory (Rev 7/15; Approved by P&T/Quality of Care) did not show 1 L bags of normal saline and lactated ringers, and 500 ml bags of normal saline and D5W were approved to be stocked in the cart.
  - An administrative record review, of the hospital’s policy and procedure for Crash Cart Expiration Handling (Date Reviewed: 1/2017) did not show: a pharmacy process to ensure all medications in the cart were checked by a pharmacist, the expiration date of the first drug to expire was indicated on the outside of the cart, the cart was stocked with only the medications approved by the hospital, and all medications in the cart were sealed by a pharmacist.
  - An administrative record review, of the hospital’s Policy and Procedures for Pharmacy Services (Revised: Aug 16) showed, 2. Practice Guidelines. "The department follows practice guidelines or recommendations promulgated by..."
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

**NAME OF PROVIDER OR SUPPLIER**: LOMPOC VALLEY MEDICAL CENTER  
**STREET ADDRESS, CITY, STATE, ZIP CODE**: 1515 E OCEAN AVENUE, LOMPPOC, CA 93436

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<th>COMPLETION DATE</th>
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| A 491 |  |  | Continued From page 40  
various Federal, State and professional organizations..."  
An administrative record review, of California Code of Regulations, Title 22. Social Security, Division 5. Licensing and Certification of Health Facilities, Home Health Agencies, Clinics and Referral Agencies, Chapter 1. General Acute Care Hospitals, Article 3. Basic Services, 70263. Pharmaceutical Service General Requirements, (f) "Supplies of drugs for use in medical emergencies only shall be immediately available at each nursing unit or service area as required...  
(2) The emergency drug supply shall be stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container shall be listed on the outside cover and shall include the earliest expiration date of any drugs within."  
A 494 |  |  | 482.25(a)(3) PHARMACY DRUG RECORDS  
Current and accurate records must be kept of the receipt and distribution of all scheduled drugs.  
This STANDARD is not met as evidenced by:  
Based on review of the hospital's Pyxis (Automated Drug Delivery Device) override reports, interview with the hospital's Director of Pharmacy (DOP), and review of the hospital's policy and procedures, the hospital failed to ensure that medications which had been overridden (removed from a Pyxis without prior review of the specific medication by a Pharmacist), that the Nurse's reasons for removing these drugs had been justified and documented. The hospital staff had also overridden medication from the hospital's Pyxis |  |  |  |  |  |

**DATE SURVEY COMPLETED**: 02/10/2017
## A 494

Continued From page 41
during the Pharmacy's hours of operation contrary to the hospital's policy and procedures.

**Findings:**

Review of the hospital's "Profile Override" report on 2/8/17 at 12:15 p.m. with the DOP revealed that hospital's Nursing staff had overridden medications from the hospital's Pyxis during the Pharmacy's normal (open) hours of operation. The Pharmacy's policy and procedure entitled: "Policy and Procedures for the Operation of the Pyxis Automated Medication Dispensing System", dated 1/17, stated: "c. Nursing directors, house supervisors and charge Nurses can override...when the Pharmacy is closed...Overrides shall be done only when a pharmacist first does review cannot be accomplished in a timely manner to prevent patient harm or well-being."

Further review of the hospital's "Profile Override" list for narcotic drugs only on 2/8/17 revealed seven (7) overrides which had occurred during the last 30 days (from 1/9/17 to 2/8/17, contrary to the hospital's policy above. Interview with the DOP on 2/6/17 at 11 a.m. revealed that the Pharmacy's hours of operation were Monday through Friday 6:30 a.m. to 7 p.m. and on Saturday through Sunday 7 a.m. to 5 p.m.

1) On 1/19/17 (on a Thursday) at 4:36 p.m. one of the Nurses providing care for the patient in room 221-ME retrieved a 10 mg vial of Morphine from the hospital's Pyxis via override while the Pharmacy was open, contrary to the hospital's policy and procedure.

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<td>A 494</td>
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<td>Continued From page 41 during the Pharmacy's hours of operation contrary to the hospital's policy and procedures.</td>
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<td>A 494</td>
<td>Continued From page 43 from the hospital's Pyxis via override while the Pharmacy was open, contrary to the hospital's policy and procedure. Additional review of the hospital's &quot;Profile Override&quot; report on 2/9/17 at noon and interview with the DOP revealed that hospital nursing staff which were overriding medications from the hospitals Pyxis were not providing justification for overriding these medications, as outlined in the hospital's policy and procedures. During the interview with the Director of Pharmacy on 2/9/17 at noon, the DOP indicated that the terms: &quot;Emergent Need- Not on the list&quot;, was not a sufficient to justification for overriding the following medications. The Pharmacy's policy and procedure entitled: &quot;Policy and Procedures for the Operation of the Pyxis Automated Medication Dispensing System&quot;, dated 1/17, stated: &quot;...If the override function is used, the nurse must specify the reason the medication was removed...&quot; Interview with the hospital's DOP on 2/9/17 at noon confirmed that the Nursing staff had not provided the necessary justification for the removal of the following override drugs from the hospital's Pyxis as overrides. The following are examples of what the hospital's DOP termed &quot;unjustified&quot; Nursing overrides: 1) On 1/18/17 at 10:24 p.m. the Nurse caring for the patient in room 03-LP overrode Oxycodeone/Tylenol (Percocet) 5/325 mg two tablets. The Nurse provided the following documentation as her/his reason for the override: &quot;Emergent Need-Not on List.&quot; The Nurse failed to specify/justify the patient's need for this</td>
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| A 494 | Continued From page 44 medication without Pharmacist first review.  
2) On 1/19/17 at 6:08 a.m. the Nurse caring for the patient in room 03-LP overrode Oxycodone/Tylenol (Percocet) 5/325 mg two tablets. The Nurse only provided the following documentation as her/his reason for the override: "Emergent Need-Not on List." The Nurse failed to specify/justify the patient's need for this medication without Pharmacist first review.  
3) On 1/20/17 at 4:52 p.m. the Nurse caring for the patient in room 03-LP overrode Oxycodone/Tylenol (Percocet) 5/325 mg two tablets. The Nurse only provided the following documentation as her/his reason for the override: "Emergent Need-Not on List." The Nurse failed to specify/justify the patient's need for this medication, without Pharmacist first review.  
4) On 1/17/17 at 9:05 p.m. the Nurse caring for the patient in room 247-LP overrode a Dilaudid 2 mg vial. The Nurse only provided the following documentation as her/his reason for the override: "Emergent Need-Not on List." The Nurse failed to specify/justify the patient's need for this medication, without Pharmacist first review.  
5) On 1/21/17 at 12:25 a.m. the Nurse caring for the patient in room 2-DO overrode a Fentanyl 100 mcg ampule. The Nurse only provided the following documentation as her/his reason for the override: "Emergent Need-Not on List." The Nurse failed to specify/justify the patient's need for this medication, without Pharmacist first review.  
6) On 1/21/17 at 1:49 a.m. the Nurse caring for
Continued From page 45

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<tr>
<td>A 494</td>
<td>the patient in room 3.2-D5 overrode Hydrocodone/Tylenol (Norco) 5/325 mg two tablets. The Nurse only provided the following documentation as her/his reason for the override: &quot;Emergent Need-Not on List.&quot; The Nurse failed to specify/justify the patient's need for this medication without Pharmacist first review.</td>
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<td>7) On 1/18/17 at 4:28 p.m. the Nurse caring for the patient in room 06-LP overrode a Fentanyl 100 mcg ampule. The Nurse only provided the following documentation as her/his reason for the override: &quot;Emergent Need-Not on List.&quot; The Nurse failed to specify/justify the patient's need for this medication without Pharmacist first review.</td>
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<td>8) On 1/18/17 at 4:45 p.m. the Nurse caring for the patient in room 06-LP overrode a Fentanyl 100 mcg ampule. The Nurse only provided the following documentation as her/his reason for the override: &quot;Emergent Need-Not on List.&quot; The Nurse failed to specify/justify the patient's need for this medication without Pharmacist first review.</td>
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<td>9) On 1/19/17 at 1:38 a.m. the Nurse caring for the patient in room 3.1-E4 overrode Hydrocodone/Tylenol (Norco) 5/325 mg two tablets. The Nurse only provided the following documentation as her/his reason for the override: &quot;Emergent Need-Not on List.&quot; The Nurse failed to specify/justify the patient's need for this medication without Pharmacist first review.</td>
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<td>10) On 1/19/17 at 6:53 a.m. the Nurse caring for the patient in room 3.1-E4 overrode Hydrocodone/Tylenol (Norco) 5/325 mg two</td>
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<td>Continued From page 46 tablets. The Nurse only provided the following documentation as her/his reason for the override: &quot;Emergent Need-Not on List.&quot; The Nurse failed to specify/justify the patient's need for this medication without Pharmacist first review.</td>
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<td>11) On 2/2/17 at 1:57 p.m. the Nurse caring for the patient in room 3.1-E4 overrode Fentanyl 100 mcg ampule. The Nurse only provided the following documentation as her/his reason for the override: &quot;Emergent Psychotherapeutic-Not on List.&quot; The Nurse failed to specify/justify the patient's need for this medication, without Pharmacist first review.</td>
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<td>12) On 1/29/17 at 5:21 p.m. the Nurse caring for the patient in room 01-LP overrode Oxycodone/Tylenol (Percocet) 5/325 mg two tablets. The Nurse only provided the following documentation as her/his reason for the override: &quot;Emergent Need-Not on List.&quot; The Nurse failed to specify/justify the patient's need for this medication, without Pharmacist first review.</td>
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<td>The examples above are just a few examples from the hospital's controlled drug override list.</td>
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<td>482.25(b)(1) PHARMACIST SUPERVISION OF SERVICES</td>
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<td>All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.</td>
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<td>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the hospital failed to ensure pharmaceutical sterile (germ free) compounding</td>
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### Statement of Deficiencies and Plan of Correction

#### Provider/Supplier/CLIA Identification Number:
- **050110**

**DATE SURVEY COMPLETED:** 02/10/2017

**Name of Provider or Supplier:** Lompoc Valley Medical Center

**Street Address, City, State, Zip Code:** 1515 E Ocean Avenue, Lompoc, CA 93436

#### Summary Statement of Deficiencies

**Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information**

<table>
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<tr>
<th>Deficiency Number</th>
<th>Description</th>
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<td>A 501</td>
<td>Continued From page 47 (mixing) services were provided in a safe manner as evidenced by:</td>
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<td>1. The hospital failed to ensure the pharmacy's viable (living) airborne sample reports, from the sterile intravenous (IV, directly into a vein) compounding area, were sent to the infection preventionist for identification of potential pathogens (microorganisms causing disease) in the hospital's patient population. The pharmacy's sterile IV compounding area was tested for viable airborne microorganisms twice in the past year. Both tests came back positive for microorganisms. The test results were not sent to the hospital's infection preventionist for identification of potential pathogens in the hospital's patient population. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP&lt;797&gt;.</td>
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<td>2. The hospital failed to ensure the pharmacy's sterile intravenous (IV, directly into a vein) compounding area was free of dust, debris, and black sticky material. The ante-room (area to prepare for mixing IVs) and buffer room (area for mixing sterile IVs) contained dust and debris on flat surfaces and in plastic bins. The ante-room had black material stuck to the floor. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP&lt;797&gt;.</td>
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<td>3. The hospital failed to ensure the intravenous (IV, directly into a vein) compounding hood (device to maintain sterile work area) was</td>
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**Event ID:** U1C711  
**Facility ID:** CA050000018  
**If continuation sheet:** Page 48 of 128
### A 501

The IV hood was cleaned with non-sterile alcohol and an opened bottle of water. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>.

4. The hospital failed to ensure the ceiling fixtures in the sterile intravenous (IV, directly into a vein) compounding area were sealed against the surface. In the ante-room (area to prepare for mixing IVs) and buffer room (area for mixing IVs) the gaps between the fixtures and the ceiling were not sealed. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>.

5. The hospital failed to ensure documented competency (ability to do a task successfully) of the staff that cleaned the sterile intravenous (IV, directly into a vein) compounding (mixing) area. The EVS (environmental services) competency checklist did not include the specific duties required for cleaning of the sterile IV compounding areas. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>.

6. The hospital failed to ensure the EVS (environmental services) cleaning check list documented the intravenous (IV, directly into a vein) sterile compounding area was serviced daily for the past month. These failures resulted in the potential, over the past year, for 5000 patients to be exposed to 3296 IV medications that were mixed in an area that did not meet all the requirements of USP<797>. 
### Statement of Deficiencies and Plan of Correction

**Name of Provider or Supplier:** Lompoc Valley Medical Center  
**Street Address, City, State, Zip Code:** 1515 E Ocean Avenue, Lompoc, CA 93436

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<td>A 501</td>
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<td>in the potential patients to be exposed to IV medications that were mixed in an area that did not meet the cleaning requirements of the hospital.</td>
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<td>7.</td>
<td>The hospital failed to ensure the sterile intravenous (IV, directly into a vein) compounding area was cleaned by competent (ability to do a task successfully) environmental services (EVS) staff. The area was cleaned by EVS staff that did not have a documented competency check list for the area. These failures resulted in the potential patients to be exposed to IV medications that were mixed in an area that did not meet all the requirements of USP&lt;797&gt;.</td>
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<td>8.</td>
<td>The hospital failed to ensure the documentation of weekly cleaning of the sterile intravenous (IV, directly into a vein) compounding area. The hospital did not have records of the environmental services (EVS) tasks performed during the weekly cleaning of the area. These failures resulted in the potential patients to be exposed to IV medications that were mixed in an area that did not meet the cleaning requirements of the hospital.</td>
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<td>9.</td>
<td>The hospital failed to ensure non-essential items were excluded from the ante-room (area to prepare for mixing sterile intravenous (IV, directly into a vein) medications). Pre-mixed antibiotics were thawed on a counter next to the ante-room's sink. The sink's soap dispenser and paper towel dispenser were in the immediate area of the thawing antibiotics. These failures resulted in the potential patients to be exposed to IV medications that were mixed in an area that did not meet the requirements of the hospital's</td>
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Findings:

1. During a concurrent interview and record review, on 2/7/17 at 3:30 p.m., Pharmacist (Pharm 1) identified the May 2016 Pharmacy Services Semi-Annual Report to the Pharmacy & Therapeutics Committee and the November 2016 Pharmacy Services Annual Report to the Pharmacy & Therapeutics Committee. Inspection of the reports did not show quality measures (indicator of the quality) from the sterile IV compounding program were reported to the Pharmacy & Therapeutics Committee. Pharm 1 reviewed the reports and acknowledged the two reports did not document quality measures were reported to the P & T committee. Continuing the interview, Pharm 1 identified the Clean Air Certification, Viable Air and Surface Environmental Report, dated June 28, 2016 and December 21, 2016. Inspection of the reports showed Bacillus sp (microorganism, bacteria) and Staphlococcus coagulase (-) (microorganism, bacteria) grew from the air sample taken on December 21 and staphylococcus coagulase (-) (microorganism, bacteria), Bacillus sp (microorganism, bacteria), and Micrococcus sp (microorganism, bacteria), grew from the air sample taken on June 28. Pharm 1 was asked to describe the process for reviewing the results of the two tests. His description did not include that the hospital's infection control professional reviewed the results.

During a concurrent interview and record review, on 2/9/17 at 9:40 a.m., Registered Nurse (LN 1)
A 501 Continued From page 51

and Pharm 1 identified a document showing 3296 IVs were compounded in the pharmacy from 2/8/16 to 2/7/17. LN 1 was asked for the number of patients admitted to the hospital over the past year. LN 1 stated approximately 5000 patients were admitted in the last year.

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, General "The intent of this document is to prevent harm to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins...in compounded sterile preparations (CSPs)." Further review showed, Environmental quality and Control, Environmental Monitoring & Maintenance...6. Any CFU (colony forming unit) counts above action levels or any potential pathogens regardless of CFU shall be remedied immediately with a deep clean of the environment, review of adequacy of cleaning procedures, operational procedures, and air filtration efficiency in consultation with the infection preventionist for the positive environments. Re-sampling shall be performed to determine if any changes made have provided resolution to the positive tests."

The United States Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the quality, purity, identity, and strength of medicines. USP's drug standards are enforceable in the United States by the Food and Drug Administration and are published in the United States Pharmacopeia/National Formulary (USP 35/NF 30). The USP revised general chapter <797> entitled PHARMACEUTICAL COMPOUNDING (mixed)-STERILE (germ free)
### A. BUILDING ____________________________

**NAME OF PROVIDER OR SUPPLIER**
LOMPOC VALLEY MEDICAL CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**
1515 E OCEAN AVENUE
LOMPOC, CA 93436

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<td>A 501</td>
<td>Continued From page 52 PREPARATIONS (CSP) documents in the Introduction that &quot;The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial toxins...&quot; [Adherence to these practice and quality standards allows the hospital to assign beyond use dates (date beyond which a CSP cannot be started) to CSPs as described in USP &lt;797&gt;.] An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 60) showed, Action Levels, Documentation, and Data Evaluation, &quot;The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted...Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered as each sampling location and trended over time. The numbers in Table 4 should be used only as guidelines. Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as cfu using an impaction air...</td>
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**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:
050110

(X2) MULTIPLE CONSTRUCTION
A. BUILDING ____________________________
B. WING ____________________________

(X3) DATE SURVEY COMPLETED
02/10/2017
A 501 Continued From page 53

sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist."

2. During a concurrent tour and interview, on 2/6/17 at 11:50 a.m., Pharmacist (Pharm 1) identified the sterile intravenous compounding suite. The suite consisted of an ante-room (area to prepare for mixing IVs) and a buffer room (area to mix IVs). The ante-room was separated from the pharmacy by walls and a door. The buffer room was separated from the ante-room by walls and a door. Inside the buffer room was a compounding hood (device to maintain a germ free work area). Pharm 1 stated the hood was used to mixed low and medium risk level sterile IV medications.

During a concurrent observation and interview, on 2/6/17 at 12:25 p.m., Pharm 1 identified the ante-room. Shelving was attached to the walls. Two large carts were stored against a wall. A small cart was stored in the middle of the room. Large blue plastic bins were stored on the floor. Inspection of the top flat metal surfaces of the storage cabinets showed they were covered with a layer of grey fibers and dust. Inspection of the clindamycin (antibiotic) 600mg (milligram)/4ml (milliliter) storage bin showed dust and debris on the inside bottom. Inspection under the large cart, near the door, showed flecks of blue and white material on the floor. Inspection of the floor, near the other large cart, showed several spots
A 501

Continued From page 54

of pencil eraser sized material stuck to the floor. The material was sticky and black. Inspection of the blue bin used to store 15% amino acids 1000 ml showed a layer of grey fibers and dust on the bottom surface. Pharm 1 acknowledged the above observations.

During a concurrent observation and interview, on 2/6/17 at 1:10 p.m., in the buffer room, Pharmacy Tech (Pharm Tech 1) identified a black rubber floor mat. Inspection of the underside of the mat showed debris was stuck to the bottom. Pharm Tech 1 acknowledged the above observation.

During an interview, on 2/6/17 at 1:20 p.m., Pharm 1 was asked to describe the cleaning process in the IV compounding suite. Pharm 1 description included the pharmacy relied upon environmental services to clean the ante-room and buffer room. Pharm 1 was asked if the ante-room and buffer room were cleaned to meet the pharmacy's expectation. Pharm 1 stated the IV compounding suite was not cleaned to meet the pharmacy's expectation.

During a concurrent interview and record review, on 2/9/17 at 9:40 a.m., Registered Nurse (LN 1) and Pharm 1 identified a document showing 3296 IVs were compounded in the pharmacy from 2/8/16 to 2/7/17. LN 1 was asked for the number of patients admitted to the hospital over the past year. LN 1 stated approximately 5000 patients were admitted in the last year.

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, General "The
A 501

Continued From page 55

intent of this document is to prevent harm to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins...in compounded sterile preparations (CSPs)." Further review showed, Cleaning and Sanitizing Workspaces, 2. "Cleaning and sanitizing of the anteroom area is performed daily by trained and supervised custodial personnel., 3. Storage shelving will be emptied of all supplies and cleaned and sanitized monthly., 4. The Floor of the compounding area (IV prep room and ante areas) will be cleaned by mopping once daily when no aseptic operations are in progress. Mopping may be performed by trained custodial personnel, per current hospital guidelines for cleaning and sanitizing surgery limited access areas and the clothing considered appropriate for that activity."

The United States Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the quality, purity, identity, and strength of medicines. USP’s drug standards are enforceable in the United States by the Food and Drug Administration and are published in the United States Pharmacopeia/National Formulary (USP 35/NF 30). The USP revised general chapter <797> entitled PHARMACEUTICAL COMPOUNDING (mixed)-STERILE (germ free) PREPARATIONS (CSP) documents in the Introduction that "The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial toxins..."

[Adherence to these practice and quality standards allows the hospital to assign beyond use dates (date beyond which a CSP cannot be]
A 501 Continued From page 56

started) to CSPs as described in USP <797>.

An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 56) showed, Cleaning and Disinfecting the Compounding Area, "Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination. The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 compounding areas for exposure of critical sites as well as buffer areas, ante-areas..."

3. During a concurrent tour and interview, on 2/6/17 at 11:50 a.m., Pharmacist (Pharm 1) identified the sterile intravenous compounding suite. The suite consisted of an ante-room (area to prepare for mixing sterile IVs) and a buffer room (area to mix sterile IVs). The ante-room was separated from the pharmacy by walls and a door. The buffer room was separated from the ante-room by walls and a door. Inside the buffer room was a compounding hood. Pharm 1 stated the hood was used to mixed low and medium risk level sterile IV medications.

During an interview, on 2/6/17 at 12:35 p.m. Pharm 1 was asked to describe the professional standards used to support the hospital's sterile IV compounding process. Pharm 1 stated the hospital uses USP<797>."

During a concurrent tour, interview, and record review, on 2/6/17 at 12:45 p.m., in the buffer room, Pharmacy Tech (Pharm Tech 1) identified,
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**SUMMARY STATEMENT OF DEFICIENCIES**

(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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**PROVIDER'S PLAN OF CORRECTION**

(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

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**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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**NAME OF PROVIDER OR SUPPLIER**

LOMPOC VALLEY MEDICAL CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**

1515 E OCEAN AVENUE
LOMPOC, CA  93436

**A 501 Continued From page 57**

next to the hood, a supply cart. On the top of the cart were a refillable spray bottle of alcohol and an opened half full bottle of sterile water. Pharm Tech 1 was asked to describe how the alcohol and water were used. Pharm Tech 1 stated the alcohol and water were used to clean the inside surface of the hood. Pharm Tech 1’s description included that the spray bottle was refilled from a supply in the ante-room. In addition, Pharm Tech 1 stated the water bottle was used until it was empty, which took about 7 days. Inspection of the label on the sterile water showed "Discard Unused Portion [sterility is no longer guaranteed]." In the ante-room Pharm Tech 1 identified the alcohol bottle used to fill the spray bottle. Inspection of the alcohol bottle did not show it was sterile alcohol.

During a concurrent interview and record review, on 2/9/17 at 9:40 a.m., Registered Nurse (LN 1) and Pharm 1 identified a document showing 3296 IVs were compounded in the pharmacy from 2/8/16 to 2/7/17. LN 1 was asked for the number of patients admitted to the hospital over the past year. LN 1 stated approximately 5000 patients were admitted in the last year.

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, General "The intent of this document is to prevent harm to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins...in compounded sterile preparations (CSPs)." Further review showed, Cleaning and Sanitizing Workspaces, 1. "Work surfaces in the IV prep room will be cleaned and at the beginning of shift, end of shift, between each shift."
**SUMMARY STATEMENT OF DEFICIENCIES**

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**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

A 501 Continued From page 58

batch and every 30 minutes during continuous compounding., a. Cleaning procedure:...1) Clean with sterile water and wipe down with dry cloth."

Further review showed, Standard Operating Procedures, "These procedures are designed to ensure the quality of the environment in which a CSP is prepared...12. At the beginning of each compounding activity session, and after liquids are spilled, the surfaces of the direct compounding environment will be sanitized with sterile 70% isopropyl alcohol (IPA) using a nonlintering wipe."

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An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 56) showed, Cleaning and Disinfecting the Compounding Area,
**A 501** Continued From page 59

"Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination. The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 (air quality) compounding areas for exposure of critical sites...Surfaces in LAFWs (hood)...which are intimate to the exposure of critical sites, require disinfecting more frequently...Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; for example, water-soluble solid residues are removed with sterile water (for injection or irrigation) and low-shedding wipes. This shall be followed by wiping with a reside-free disinfecting agent such as sterile 70% IPS (alcohol), which is allowed to dry before compounding begins."

4. During a concurrent tour and interview, on 2/6/17 at 11:50 a.m., Pharmacist (Pharm 1) identified the sterile intravenous compounding suite. The suite consisted of an ante-room and a buffer room. The ante-room was separated from the pharmacy by walls and a door. The buffer room was separated from the ante-room by walls and a door. Inside the buffer room was a compounding hood. Pharm 1 stated the hood (device to maintain a germ free work area) was used to mixed low and medium risk level sterile IV medications.

During a concurrent observation and interview, on 2/6/17 at 12:35 p.m. Pharm 1 identified the
A 501 Continued From page 60

ante-room. Inspection of the ceiling lights and air diffuser showed unsealed spaces between the fixtures and the ceiling. Pharm 1 acknowledged the unsealed space between the ceiling and fixtures. Pharm 1 was asked to describe the professional standards used to support the hospital's sterile IV compounding process. Pharm 1 stated the hospital uses USP<797>.

During a concurrent tour and interview, on 2/6/17 at 12:45 p.m., Pharmacy Tech (Pharm Tech 1) identified the buffer room. Inspection of the ceiling lights and air diffuser showed an unsealed space between the fixtures and the ceiling. Pharm Tech 1 acknowledged the unsealed space between the fixtures and the ceiling.

During a concurrent interview and record review, on 2/9/17 at 9:40 a.m., Registered Nurse (LN 1) and Pharm 1 identified a document showing 3296 IVs were compounded in the pharmacy from 2/8/16 to 2/7/17. LN 1 was asked for the number of patients admitted to the hospital over the past year. LN 1 stated approximately 5000 patients were admitted in the last year.

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, General "The intent of this document is to prevent harm to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins...in compounded sterile preparations (CSPs)." Further review showed, Environmental Quality and Control, 4. "Dust-collecting overhangs, such as ceiling utility pipes, or ledges, such as windowsills, should be avoided. The exterior lens surface of ceiling lighting..."
**A 501** Continued From page 61

fixtures should be smooth, mounted flush, and sealed...5. Any other penetrations through the ceiling or walls should be sealed.*

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An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 52-53) showed, Facility Design and Environmental Controls, “The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate...The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other
A 501 Continued From page 62 penetrations through the ceiling or walls shall be sealed.

5. During a concurrent tour and interview, on 2/6/17 at 11:50 a.m., Pharmacist (Pharm 1) identified the sterile intravenous compounding suite. The suite consisted of an ante-room (area to prepare for mixing IVs) and a buffer room (area to mix IVs). The ante-room was separated from the pharmacy by walls and a door. The buffer room was separated from the ante-room by walls and a door. Inside the buffer room was a compounding hood (device to maintain a germ free work area). Pharm 1 stated the hood was used to mixed low and medium risk level sterile IV medications.

During a concurrent observation and interview, on 2/6/17 at 12/25 p.m., Pharm 1 identified the ante-room. Shelving was attached to the walls. Two large carts were stored against a wall. A small cart was stored in the middle of the room. Large blue plastic bins were stored on the floor. Inspection of the top flat metal surfaces of the storage cabinets showed they were covered with a layer of grey fibers and dust. Inspection of the clindamycin (antibiotic) 600mg (milligram)/4ml (milliliter) storage bin showed dust and debris on the inside bottom. Inspection under the large cart, near the door, showed flecks of blue and white material on the floor. Inspection of the floor, near the other large cart, showed several spots of pencil eraser sized material stuck to the floor. The material was sticky and black. Inspection of the blue bin used to store 15% amino acids 1000 ml showed a layer of grey fibers and dust on the bottom surface. Pharm 1 acknowledged the above observations.
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During a concurrent observation and interview, on 2/6/17 at 1:10 p.m., in the buffer room, Pharmacy Tech (Pharm Tech 1) identified a black rubber floor mat. Inspection of the underside of the mat showed debris was stuck to the bottom. Pharm Tech 1 acknowledged the above observation.

During an interview, on 2/6/17 at 1:20 p.m., Pharm 1 was asked to describe the cleaning process in the IV compounding suite. Pharm 1 description included the pharmacy relied upon environmental services to clean the ante-room and buffer room. Pharm 1 was asked if the ante-room and buffer room were cleaned to meet the pharmacy’s expectation. Pharm 1 stated the IV compounding suite was not cleaned to meet the pharmacy’s expectation.

During a concurrent interview and record review, on 2/9/17 at 9:40 a.m., Registered Nurse (LN 1) and Pharm 1 identified a document showing 3296 IVs were compounded in the pharmacy from 2/8/16 to 2/7/17. LN 1 was asked for the
A 501  Continued From page 64
number of patients admitted to the hospital over
the past year. LN 1 stated approximately 5000
patients were admitted in the last year.

An administrative record review, of the hospital's
policy and procedure for Sterile Compounding
(Date Revised: 10/16) showed, General "The
intent of this document is to prevent harm to
patients that could result from microbial
contamination (nonsterility), excessive bacterial
endotoxins...in compounded sterile preparations
(CSPs)." Further review showed, Environmental
Quality and Control, Cleaning and Sanitizing
Workspaces...Prior to cleaning and sanitizing,
training and competency determination of any
new staff member shall be completed by another
staff member deemed to be competent. The
records of this competency determination will be
kept on file by the department director."

The United States Pharmacopeial Convention
(USP) is a scientific nonprofit organization that
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FORM CMS-2567(02-99) Previous Versions Obsolete Event ID: U1C711 Facility ID: CA050000018 If continuation sheet Page 65 of 128
A 501 Continued From page 65

use dates (date beyond which a CSP cannot be started) to CSPs as described in USP <797>.

An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 58) showed, Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures, "In the event that cleaning and disinfecting procedures are also performed by other support personnel (e.g., institutional environmental services, housekeeping), through training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert."

6. During a concurrent tour and interview, on 2/6/17 at 11:50 a.m., Pharmacist (Pharm 1) identified the sterile intravenous compounding suite. The suite consisted of an ante-room (area to prepare for mixing IVs) and a buffer room (area to mix IVs). The ante-room was separated from the pharmacy by walls and a door. The buffer room was separated from the ante-room by walls and a door. Inside the buffer room was a compounding hood (device to maintain a germ free work area). Pharm 1 stated the hood was used to mixed low and medium risk level sterile IV medications.

During a concurrent observation and interview, on 2/6/17 at 12:25 p.m., Pharm 1 identified the
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During an interview, on 2/6/17 at 1:20 p.m., Pharm 1 was asked to describe the cleaning process in the IV compounding suite. Pharm 1 description included the pharmacy relied upon environmental services to clean the ante-room and buffer room. Pharm 1 was asked if the ante-room and buffer room were cleaned to meet the pharmacy's expectation. Pharm 1 stated the IV compounding suite was not cleaned to meet the pharmacy's expectation.
During a concurrent interview and record review, on 2/9/17 at 10 a.m., Pharm 1 identified the computer log for daily cleaning. Inspection of the log showed daily cleaning was documented from 2/6/16 - 2/6/17. Pharm 1 identified the Pharmacy Department Environmental Services Cleaning documents. Inspection of the Pharmacy Department Environmental Services Cleaning documents, from 1/9/17 to 2/7/17, did not show documentation the ante-room and buffer room were cleaned on 1/10, 1/15, 1/17, 1/28, 1/29, and 2/4/17. Pharm 1 acknowledged the Pharmacy Department Environmental Services Cleaning did not document the ante-room and buffer room were cleaned on 1/10, 1/15, 1/17, 1/28, 1/29, and 2/4/17.

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, General "The intent of this document is to prevent harm to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins...in compounded sterile preparations (CSPs)." Further review did not show a procedure to document on the Pharmacy Department, Environmental Services Cleaning form the daily cleaning of the ante-room and buffer room.

7. During a concurrent tour and interview, on 2/6/17 at 11:50 a.m., Pharmacist (Pharm 1) identified the sterile intravenous compounding suite. The suite consisted of an ante-room (area to prepare for mixing IVs) and a buffer room (area to mix IVs). The ante-room was separated from the pharmacy by walls and a door. The
A 501  Continued From page 68
buffer room was separated from the ante-room by walls and a door. Inside the buffer room was a compounding hood (device to maintain a germ free work area). Pharm 1 stated the hood was used to mixed low and medium risk level sterile IV medications.

During a concurrent observation and interview, on 2/6/17 at 12:25 p.m., Pharm 1 identified the ante-room. Shelving was attached to the walls. Two large carts were stored against a wall. A small cart was stored in the middle of the room. Large blue plastic bins were stored on the floor. Inspection of the top flat metal surfaces of the storage cabinets showed they were covered with a layer of grey fibers and dust. Inspection of the clindamycin (antibiotic) 600mg (milligram)/4ml (milliliter) storage bin showed dust and debris on the inside bottom. Inspection under the large cart, near the door, showed flecks of blue and white material on the floor. Inspection of the floor, near the other large cart, showed several spots of pencil eraser sized material stuck to the floor. The material was sticky and black. Inspection of the blue bin used to store 15% amino acids 1000 ml showed a layer of grey fibers and dust on the bottom surface. Pharm 1 acknowledged the above observations.

During a concurrent observation and interview, on 2/6/17 at 1:10 p.m., in the buffer room, Pharmacy Tech (Pharm Tech 1) identified a black rubber floor mat. Inspection of the underside of the mat showed debris was stuck to the bottom. Pharm Tech 1 acknowledged the above observation.

During an interview, on 2/6/17 at 1:20 p.m.,
Pharm 1 was asked to describe the cleaning process in the IV compounding suite. Pharm 1 description included the pharmacy relied upon environmental services to clean the ante-room and buffer room. Pharm 1 was asked if the ante-room and buffer room were cleaned to meet the pharmacy's expectation. Pharm 1 stated the IV compounding suite was not cleaned to meet the pharmacy's expectation.

During a concurrent interview and record review, on 2/9/17 at 10 a.m., Pharm 1 identified the Pharmacy Department Environmental Services Cleaning forms (1/9/17-2/7/17). In addition, Pharm 1 identified the Competency Checklist EVS Technician (3/16/16-current) for the EVS technicians who have cleaned the ante-room and buffer room. Review of the documents showed the ante-room and buffer room were cleaned on 1/9, 1/14, 1/22, 1/28, 1/26, 1/27, 1/30, 2/3, and 2/5/17 by an EVS technician without a documented competency checklist. Pharm 1 acknowledged the observations above.

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, General "The intent of this document is to prevent harm to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins...in compounded sterile preparations (CSPs)." Further review showed, Environmental Quality and Control, Cleaning and Sanitizing Workspaces...Prior to cleaning and sanitizing, training and competency determination of any new staff member shall be completed by another staff member deemed to be competent. The records of this competency determination will be...
A 501 Continued From page 70

kept on file by the department director."

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An administrative record review, of the 2017 USP Compounding Compendium, Current with USP 40-NF 35 (Nov 2016, Page 58) showed, Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures, "In the event that cleaning and disinfecting procedures are also performed by other support personnel (e.g., institutional environmental services, housekeeping), through training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support personnel shall routinely undergo performance evaluation of proper hand hygiene,
Continued From page 71

garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert."

8. During a concurrent tour and interview, on 2/6/17 at 11:50 a.m., Pharmacist (Pharm 1) identified the sterile intravenous compounding suite. The suite consisted of an ante-room (area to prepare for mixing IVs) and a buffer room (area to mix IVs). The ante-room was separated from the pharmacy by walls and a door. The buffer room was separated from the ante-room by walls and a door. Inside the buffer room was a compounding hood (area to prepare for mixing IVs). Pharm 1 stated the hood was used to mixed low and medium risk level sterile IV medications.

During a concurrent observation and interview, on 2/6/17 at 12/25 p.m., Pharm 1 identified the ante-room. Shelving was attached to the walls. Two large carts were stored against a wall. A small cart was stored in the middle of the room. Large blue plastic bins were stored on the floor. Inspection of the top flat metal surfaces of the storage cabinets showed they were covered with a layer of grey fibers and dust. Inspection of the clindamycin (antibiotic) 600mg (milligram)/4ml (milliliter) storage bin showed dust and debris on the inside bottom. Inspection under the large cart, near the door, showed flecks of blue and white material on the floor. Inspection of the floor, near the other large cart, showed several spots of pencil eraser sized material stuck to the floor. The material was sticky and black. Inspection of the blue bin used to store 15% amino acids 1000 ml showed a layer of grey fibers and dust on the bottom surface. Pharm 1 acknowledged the above observations.
## Summary Statement of Deficiencies

### A 501 Continued From page 72

During a concurrent observation and interview, on 2/6/17 at 1:10 p.m., in the buffer room, Pharmacy Tech (Pharm Tech 1) identified a black rubber floor mat. Inspection of the underside of the mat showed debris was stuck to the bottom. Pharm Tech 1 acknowledged the above observation.

During an interview, on 2/6/17 at 1:20 p.m., Pharm 1 was asked to describe the cleaning process in the IV compounding suite. Pharm 1 description included the pharmacy relied upon environmental services to clean the ante-room and buffer room. Pharm 1 was asked if the ante-room and buffer room were cleaned to meet the pharmacy's expectation. Pharm 1 stated the IV compounding suite was not cleaned to meet the pharmacy's expectation.

During a concurrent interview and record review, on 2/9/17 at 10 a.m., Pharm 1 identified the computer log for weekly cleaning of the ante-room and buffer room. Review of the log showed weekly cleaning was documented on 1/13/17, 1/20/17, 1/27/17, and 2/3/17. Review of the Pharmacy Department Environmental Services Cleaning documents for the dates listed above did not show the specific duties that were performed for weekly cleaning. Pharm 1 reviewed the Pharmacy Department Environmental Services Cleaning documents and acknowledged the above observations.

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, General "The intent of this document is to prevent harm to
### Statement of Deficiencies and Plan of Correction

| A 501 | Continued From page 73 patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins...in compounded sterile preparations (CSPs). Further review showed, Environmental Quality and Control, Cleaning and Sanitizing Workspaces, "The cleaning, sanitizing and organizing of the direct and contiguous compounding area (DCCA) is the responsibility of the technician and/or environmental services, and is performed as described below...5. The walls and ceiling of the compounding area will be cleaned and sanitized at a minimum weekly. This may be performed by trained and supervised custodial personnel, per current hospital guidelines for cleaning and sanitizing surgery limited access areas."

An administrative record review, of the hospital's Pharmacy Department, Environmental Services Cleaning, Summary of EVS Cleaning Responsibilities; did not show the weekly EVS cleaning responsibilities.

9. During a concurrent observation, interview, and record review, on 2/7/16 at 12:15 p.m., in the ante-room, 10 frozen doses of intravenous 750 mg (milligram) vancomycin (antibiotic) were defrosting next to the hand washing sink. Immediately above and to the left of the defrosting antibiotics was the sink's soap dispenser. Immediately above the defrosting antibiotics was the sink's paper towel dispenser. Pharmacist (Pharm 2) acknowledged the above observations.

An administrative record review, of the hospital's policy and procedure for Sterile Compounding (Date Revised: 10/16) showed, Environmental...
### Quality and Control, Critical Site Environment

"The CSP work environment is designed to have the cleanest work surfaces (LAFW (hood, device to provide a germ free work area) located in a buffer area (area for mixing IVs), which is preceded by an anteroom that provides a clean area for donning personnel barriers, such as hair covers, gloves, gowns,. Measuring, weighing, mixing, and other manipulations of nonsterile in-process CSPs are also performed in air quality of at least ISO Class 7., 1. Only the furniture, equipment, supplies, and other goods required for the tasks to be performed may be brought into this room, and they should be nonpermeable, nonshedding, and resistant to disinfectants."

### A 501 Access to Locked Areas

Only authorized personnel may have access to locked areas.

This STANDARD is not met as evidenced by:

Based on observation and interview, the hospital failed to ensure only authorized individuals had access to medications in the physical therapy unit.

This failure has the potential for loss and/or unauthorized use of medications.

Findings:

Facility policy and procedure titled, "Medication Access" dated 04/05, revised 07/16 indicated in part, "2. Policy a. All drugs and biologicals must be kept in a secure area, and locked when appropriate. A secure area means drugs and biologicals are stored in a manner to prevent unmonitored..."
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050110

(X2) MULTIPLE CONSTRUCTION

<table>
<thead>
<tr>
<th>A. BUILDING</th>
<th>PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER</th>
<th>MULTIPLE CONSTRUCTION</th>
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B. WING

(X3) DATE SURVEY COMPLETED 02/10/2017

NAME OF PROVIDER OR SUPPLIER
LOMPOC VALLEY MEDICAL CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
1515 E OCEAN AVENUE
LOMPOC, CA 93436

(X4) ID PREFIX TAG SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETION DATE</th>
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<tr>
<td></td>
<td>A 504 Continued From page 75 access by unauthorized individuals. Drugs and biologicals must be stored in areas that are not readily accessible to unauthorized persons.&quot;</td>
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During a concurrent observation of physical therapy area and interview with a licensed nurse (LN 1) on 2/6/17, at 3 p.m., in the physical therapy storage area in a unlocked cabinet opened by a physical therapy aid (PT 1) was four bottles of 500 millimeters (ML) unopened sodium chloride (solution often used to cleanse wounds) stored on shelf next to various cleaning supplies. LN 1 acknowledged cabinet was open and accessible to unauthorized personnel, LN 1 stated, "No should be locked and not together with cleaning supplies."

Further observation of physical therapy area revealed a locked mobile cabinet in the physical therapy area workout room, when asked who had a key, unlicensed medical assistant (MA 1) indicated she did. MA 1 opened the cabinet and among other items was a white bag containing three lidocaine HCl 1% epinephrine (used to locally anesthetize) 20 ml vials. MA 1 stated, "I just got a couple vials from the pharmacy and put them in there, because sometimes the surgeon's use this space and they need something to numb up the patients." In addition there was one vial of sensorcaine (anesthetic) 50 ml, three vials of bupivacaine HCl/epinephrine (anesthetic) 10 ml and multiple 18 gauge needles. MA 1 acknowledged she had access to the mobile cabinet. Further review of MA 1 job description did not indicate MA 1 had been granted authorized access to storage areas for drugs or biologicals.

A 505 482.25(b)(3) UNUSABLE DRUGS NOT USED A 505
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<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<th>COMPLETION DATE</th>
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<tr>
<td>A 505</td>
<td>Continued From page 76</td>
<td></td>
<td>Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use. This STANDARD is not met as evidenced by: Based on inspection of the hospital's patient service areas the hospital failed to ensure that several open 1000 (ml) milliliter bottles of Sterile Water for Irrigation had been discarded in accordance with the drug manufacturer's labeled instructions. Findings: Inspection of the hospital's Pharmacy Ante room (clean air room) on 2/6/17 at 12:25 p.m. revealed one open bottle of Sterile Water for Irrigation 1000 ml. Interview with the Pharmacy's (Director of Pharmacy) DOP on 2/6/17 at 12:28 p.m. and Pharm Tech 1, revealed that they were unable to determine how long this bottle of Sterile Water for irrigation had been open. The drug manufacturer's label stated: &quot;Discard unused portion&quot;, indicating that this bottle must not be kept or used after it has been initially opened. Inspection of the hospital's Pharmacy cabinet, just outside the Ante room on 2/6/17 at 3:10 p.m. revealed one bottle of 1000 ml Sterile Water for Injection which was also open for an unknown length of time. No date of opening had been marked on the outside of this container. Inspection of the hospital's (Magnetic Resonance Imaging) MRI control room on 2/6/17 at 3:55 p.m. revealed three open 1000 ml bottles of Sterile Water for Irrigation. Interview with the MRI Nurse</td>
<td>A 505</td>
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## SUMMARY STATEMENT OF DEFICIENCIES

### A 505

Continued From page 77  

(Rd2) during this inspection revealed that she was unable to determine how long these bottles of Sterile Water for Irrigation had been open. Rd2 during the interview indicated that hospital staff were unaware that these bottles of Sterile Water for Irrigation needed to discarded after being opened.

Inspection of the hospital's Emergency Room (ER) department on 2/7/17 at 12:40 p.m. revealed the following expired medications:

- *1 (one) bag of D5W with Normal Saline was found in the hospital's medication room cabinet with an expiration date of 11/16.
- *1 (one) bag of Dextrose 5% for injection 1000 ml was found with an expiration date of 1/17.

### A 618 FOOD AND DIETETIC SERVICES

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

This CONDITION is not met as evidenced by: Based on observations, staff interviews and record reviews, the hospital condition of participation for food and dietetic services was...
**A. 618 Continued From page 78**

not met as evidenced by:

1. The hospital failed to ensure that the Director of Dietary Services (DDS) was effective in the daily management of the dietary services. Cross refer A 620

2. The hospital failed to ensure that the dietary staff (Cook 3) was competent in their respective duties. This was noted when they lacked knowledge regarding the safe cooling of potentially hazardous foods (PHF). This lapse in competency resulted in unsafe food storage practices and had the potential to result in food borne illness in a susceptible patient population. Cross refer A 622

3. The hospital failed to ensure there was a well-defined disaster feeding plan in order to ensure the safety and well-being of the patients in the event of a disaster. This resulted when the hospital failed to have a food inventory consistent with the 3-day emergency menu and not all of the items on the menu had portion sizes. This had the potential to result in an inadequate nutrition in a susceptible patient population. Cross refer A 701

4. The hospital failed to ensure an enhanced protein diet was ordered by the physician responsible for the care of the patient for one patient (Patient 17). Cross refer A 630

5. The hospital failed to develop and utilize a diet manual that was specific to the hospital; included diets routinely ordered; provided accurate guidance for ordering and preparing patient meals. Cross refer A 631
6. The hospital failed to develop an effective infection control surveillance system for identifying unsafe food handling practices in the dietary department. The lack of surveillance of these unsafe food handling practices had the potential to result in a food borne illness outbreak in a highly susceptible patient population. Cross refer A 749

The cumulative effect of these systemic problems resulted in the inability of the facility's food and nutrition services to direct and staff in such a manner to ensure that the nutritional needs of the patients were met in accordance with practitioners' orders and acceptable standards of practice.

This STANDARD is not met as evidenced by: Based on observation, staff interviews and record reviews, the hospital failed to ensure that the Director of Dietary Services (DDS) was effective in the daily management of the dietary services when:

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<td>A 618</td>
<td>Continued From page 79</td>
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<tr>
<td>A 620</td>
<td>482.28(a)(1) DIRECTOR OF DIETARY SERVICES</td>
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LOMPOC VALLEY MEDICAL CENTER

1515 E OCEAN AVENUE
LOMPOC, CA 93436
**SUMMARY STATEMENT OF DEFICIENCIES**

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<td>A 620</td>
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- The lack of an effective system to monitor time/temperature control of nine of nine previously cooked foods capable of producing foodborne illness. Lack of a system to monitor foods cooling that were prepared at room temperature. Cross refer A 749

- Food Service staff of the lacked competency in cooling of potentially hazardous food. Cross refer A 622

- There was not a well-defined disaster feeding plan that met patient nutritional parameters. Cross refer A 701

- Ensured that data reported as part of the Quality Assurance Performance Improvement (QAPI) program was tracked and trended for analysis purposes with effective action plans for improved provision of care. Cross refer A 273

These failures had the potential to result in food borne illness, inadequate nutrition during a disaster, and lack of data for quality assurance measures for the department in a susceptible patient population in a hospital with a licensed bed capacity of 60.

**Findings:**

1. On 2/7/17, starting at 10:55 a.m., during an inspection of the food service operation, the following was observed:

   - Potentially hazardous foods were not being cooled in a safe manner.
## Statement of Deficiencies and Plan of Correction

**Provider/Supplier/CLIA Identification Number:** 050110

**Building:**

**Wing:**

**Date Survey Completed:** 02/10/2017

**Name of Provider or Supplier:** Lompoc Valley Medical Center

**Street Address, City, State, Zip Code:** 1515 E Ocean Avenue, Lompoc, CA 93436

### Summary Statement of Deficiencies

Each deficiency must be preceded by full regulatory or LSC identifying information.

### A 620

Continued From page 81

*Storage of foods capable of supporting bacterial growth associated with foodborne illness in an under counter refrigerator in the café.*

*The lack of an effective system to monitor the temperature of foods capable of supporting bacterial growth associated with foodborne illness in the salad bar in the café.*

**Cross Refer A 749**

**a.** During observations, interviews and record reviews in the kitchen on 2/7/17 starting at 10:55 a.m. and 2/8/17 at 9:59 a.m., multiple potentially hazardous foods (PHF) were observed with no record of being cooled down safely.

During the survey it was noted that PHFs were not being monitored for safe cooling to 41 degrees Fahrenheit (F) or less within 4 hours when prepared from ingredients at room temperature.

Potentially Hazardous Foods (PHF) are those that are capable of supporting bacterial growth associated with foodborne illness. PHF’s require time and temperature control through all phases including receiving, storage and food production. It would be the standard to ensure that hot PHF’s are consistently monitored and cooled from 135°F (degrees Fahrenheit) to 70°F within 2 hours and to 41°F or less in an additional 4 hours, a maximum total of 6 hours. Similarly, foods that are prepared from room temperature ingredients shall be monitored to ensure temperatures decrease to 41°F or below within 4 hours of preparation (Federal Food Code 2013).

According to the 2013 FDA Food Code,
A 620 Continued From page 82
potentially hazardous food (time/temperature control for safety food) shall be cooled within 4 hours to 41 degrees F or less if prepared from ingredients at ambient (room) temperature, such as reconstituted foods and canned tuna.

b. During the observations and interviews on 2/7/17 between 11:40 a.m. and 12:10 p.m., several food items on the salad bars were not being monitored throughout the day when they were being served (10:30 a.m. to 6:30 p.m.).

c. During the observations and interviews on 2/7/17 starting at 10:55 a.m. and 2/8/17 at 9:59 a.m., some PHF being held in an under the counter refrigerator in the cafe that are required to be kept at a temperature less than 41 degrees F were not being monitored or held at that temperature.

2. During the survey the dietary staff (Cook 3) was noted to lack competency in their respective duties. This was noted when they lacked knowledge regarding safe cooling of potentially hazardous foods (PHF). This lapse in competency resulted in unsafe food storage practices and had the potential to result in food borne illness in a susceptible patient population. Cross refer A 622

3. During the survey the DDS failed to ensure there was a well-defined disaster feeding plan in order to ensure the safety and well-being of the patients in the event of a disaster. This resulted when the hospital failed to have a food inventory consistent with the 3-day emergency menu and not all of the items on the menu had portion sizes. This had the potential to result in an
<table>
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<th>A 620</th>
<th>Continued From page 83 inadequate nutrition in a susceptible patient population. Cross refer A 701</th>
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<td>4. On 2/8/17 at 12:45 p.m., an interview was conducted with the Director of Dietary Services (DDS) regarding the Quality Assurance Performance Improvement (QAPI) plan for his department. The DDS stated they are doing test trays and keep a log when done and these are done mostly by the diet aids and trayline observations. He stated he puts in report and their goal is 100% and they have been doing well. The DDS was not able to show what data he reported to the Board at this time but it would be provided.</td>
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<td>On 2/9/17 at 9:50 a.m., an interview was conducted with RD 5 regarding clinical nutrition QAPI. RD 5 stated they have not been monitoring, collecting or reporting anything for clinical nutrition. Developing, performing and evaluating of continuous quality improvement program was within the scope of the Registered Dietitian position description. Cross refer A 273</td>
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<td>Review of the Dietary Services Director job description, showed some of his responsibility was to: oversees the procurement, storage, productions and distribution of all supplies and meals to the patients and cafeteria; selects, trains, supervises and evaluates department staff; develops, enforces and evaluates department policies and procedures; plans and/or participates in-services for department staff; and performance improvement activities.</td>
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<tr>
<th>A 622</th>
<th>482.28(a)(3) COMPETENT DIETARY STAFF</th>
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<td>There must be administrative and technical</td>
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<td>A 622</td>
<td>Continued From page 84 personnel competent in their respective duties.</td>
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<td>This STANDARD is not met as evidenced by:</td>
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<td>Based on observation, staff interviews and record reviews, the hospital failed to ensure that the dietary staff (Cook 3) was competent in their respective duties. This was noted when they lacked knowledge regarding the safe cooling of potentially hazardous foods (PHF). This lapse in competency had the potential to result in food borne illness in a susceptible patient population. Cross refer A 749</td>
</tr>
<tr>
<td></td>
<td>Findings: Potentially Hazardous Foods (PHF) are those that are capable of supporting bacterial growth associated with foodborne illness. PHF’s require time and temperature control through all phases including receiving, storage and food production. It would be the standard to ensure that hot PHF’s are consistently monitored and cooled from 135°F (degrees Fahrenheit) to 70°F within 2 hours and to 41°F or less in an additional 4 hours, a maximum total of 6 hours. Similarly, foods that are prepared from room temperature ingredients shall be monitored to ensure temperatures decrease to 41°F or below within 4 hours of preparation (Federal Food Code 2013).</td>
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<td>During the initial tour of the kitchen in the hospital on 2/7/17 starting at 10:55 a.m., the following items were observed in the walk-in refrigerator: cooked pork dated 2/6/17; cooked scrambled eggs and cooked potatoes labeled as breakfast dated 2/6 and use by 2/11; cheese sauce dated 2/6 with a use by date of 2/11 and a temperature of 43.5°F; marinara sauce dated 2/5 and use by</td>
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Form CMS-2567(02-99) Previous Versions Obsolete  
Event ID: U1C711  
Facility ID: CA050000018  
If continuation sheet Page 85 of 128
### SUMMARY STATEMENT OF DEFICIENCIES

#### A 622

Continued From page 85

2/10. A concurrent interview was conducted with the Director of Dietary Services (DDS) when he stated they make the sauces at the hospital and they were not from a can. The DDS stated foods are good for 5 days once it is opened or prepared.

On 2/7/17 at 11:40 a.m. in the cafe under the grill there were reach-in refrigerator drawers. In one of the drawers the following items were observed: cooked turkey burger patties dated 2/6 that were 42.8°F, cooked veggie burger patties dated 2/6 with a temperature of 43.3°F, and cooked hamburger patties dated 2/6 with a temperature of 42.9°F. A concurrent interview was conducted with the DDS, he stated that the food items would stay in the reach in drawers throughout the day and night. The DDS stated these foods are precooked in advance.

On 2/7/17 at 12:45 p.m. an interview was conducted with Cook 1 and Cook 2 regarding cool down procedures for foods cooked in advance. Cook 1 stated they cook quite a few items in advance then would cool down and write in a log. Cook 1 stated he would start the cooling process then the PM cook finishes it when his shift is over. When asked what the cooling procedure was, he stated in 2 hours the food should be 70 degrees F then they have 4 more hours to get the food to 41 degrees F or less. Cook 1 stated they would sometimes keep breakfast leftovers then he would use that to put in breakfast burritos and served another day. Cook 1 said they only put hot items on the log. When asked about the food items dated on 2/6 in the walk-in refrigerator, Cook 1 looked at the log and no items were dated 2/6. Cook 1 stated they...
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER:**
LOMPOC VALLEY MEDICAL CENTER

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<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
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<td>A 622</td>
<td>Continued From page 86</td>
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A new cook over the weekend and he must not have put any food items on the log so when he came to work on Monday he thought the date was the 4th instead of the 6th. Cook 1 stated the pork loin was on the log just with the incorrect date. Cook 2 was asked what she knew about the cool down procedures. Cook 2 stated she just takes one temperature and writes the temperature on the log. Cook 2 stated she usually takes the temperature around 2:30-3:30 but doesn't always put the time next to the temperature. Cook 2 stated she does not go back to verify if the food ever reaches 41 degrees F. Cook 2 stated she was not aware that the food had to get to 41 degrees F in 4 hours. Regarding the pork loin on the log, Cook 2 stated she thought the temperature was taken around 3 p.m..

Review of the untitled Cooling Log dated 1/30 through 2/7 showed, pork loin dated "2/6" at 1:00 it was 167°F, 1:00 it was 66°F then there was no time on last column but the temperature showed 50°F. There was potato bar dated "2/6" and showed at 11:15 it was 180°F, at 1:15 it was 70°F then the last column showed the temperature was 58°F with no time on it. Further review of the log dated from 9/29/16 until 2/7/17, showed that 131 out of 141 food items did not reach 41°F or less.

On 2/8/17 at 12:45 p.m. an interview was conducted with the DDS regarding his role as the director. The DDS stated he is supposed to have in-services with the staff every month but due to lack of staffing it has not happened as often. The DDS stated he had a staff meeting with the department last month dated 1/12/17 and the...
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<td>A 622</td>
<td>Continued From page 87</td>
<td>time before that was 4/7/16. The DDS stated he had not had any in-services on cool down in the last year.</td>
<td>A 622</td>
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<td>A 630</td>
<td>482.28(b)(2) DIETS</td>
<td>All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals. This STANDARD is not met as evidenced by: Based on observation, staff interviews and record review the hospital failed to ensure an enhanced protein diet was ordered by the physician responsible for the care of the patient for one patient (Patient 17). Findings: On 2/7/17 starting at 12:10 p.m., an observation of the lunch meal trayline was conducted in the presence of the Registered Dietitian (RD) 4. Patient 17's diet order was reviewed and showed he was receiving a Cardiac, puree, enhanced diet with ensure three times a day. The RD 4 stated enhanced meant they got 1 scoop of protein powder in a food item for each meal. Patient 17's medical record was reviewed. Patient 17 was admitted to the hospital with a diagnosis of sepsis (serious medical condition caused by an overwhelming immune response to infection). Review of the physician's orders dated 2/2/17, showed a cardiac dysphagia (problems chewing and swallowing) 1 (puree) diet. Physician's orders dated 2/6/17 showed</td>
<td>A 630</td>
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### Statement of Deficiencies and Plan of Correction

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<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Deficiency)</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>A 630</td>
<td></td>
<td></td>
<td>Continued From page 88 cardiac dysphagia 1 pureed diet and Ensure (nutrition supplement) three times a day. Review of the Likes/Dislikes entered in the electronic medical record dated 2/2/17 showed RD 5 entered &quot;Enhanced. Ensure (nutrition supplement) each meal..&quot;</td>
<td>A 630</td>
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On 2/8/17 starting at 10:58 a.m., an interview was conducted with Registered Dietitian (RD 4. RD 4 stated the RD's will enter in the computer under the likes and dislikes section things they discuss with the patient so Patient 17 probably preferred the juice supplement so will give ensure and they started them on getting protein powder with meals as well. . RD 4 stated enhanced protein diet is abbreviated by enhanced. This is how they communicate with the kitchen to make sure they get specific items. The Diet Aid will meet with patient and try to determine what food items the protein powder will go into, examples are applesauce, or hot item like mashed potatoes, soup etc. When asked for a description of the diet, the RD 4 stated they probably needed to update the document titled "Therapeutic Diet Details" since it called it a High Protein Diet not enhanced. (Cross Refer A-631)

On 2/9/17 at 10 a.m., an interview was conducted with RD 5. RD 5 stated they do not get a physician's order for the enhanced portion of the diet, they just enter in the computer and the kitchen will carry out. RD 5 looked in the electronic medical record and stated yes it could be ordered as a Protein Enhanced diet in the medical record. RD 5 stated she did not realize she was ordering a diet without a physician's order.
## Statement of Deficiencies and Plan of Correction

### A. Building _____________________________

**Name of Provider or Supplier:** Lompoc Valley Medical Center  
**Street Address, City, State, Zip Code:** 1515 E Ocean Avenue, Lompoc, CA 93436

### B. Wing _____________________________

**Provider/Supplier/CLIA Identification Number:** 050110

**Date Survey Completed:** 02/10/2017

### Provider's Plan of Correction

<table>
<thead>
<tr>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>ID</th>
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<th>Tag</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Deficiency)</th>
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<tr>
<td>A 630</td>
<td>Continued From page 89</td>
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<td>Review of the hospital's policy and procedure titled &quot;General Responsibilities of Physician/Nutritional Services Interactions&quot; revised 7/1/15, showed the physician will enter the diet order in the electronic medical record. In the State of California, the RD business and profession code does not allow the RD to write diet orders. (BUSINESS AND PROFESSIONS CODE SECTION 2585-2586.8)</td>
<td>A 630</td>
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<tr>
<td>A 631</td>
<td>482.28(b)(3) Therapeutic Diet Manual</td>
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<td>A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel. This failure had the potential to result in a lack of consistency and communication concerning the diets among medical, nursing and dietary staff. This failure had the potential to affect the patient census. Findings: Diet manuals establish a common language and practice for physicians and other healthcare professionals to use when providing nutrition care to patients. The diet manual includes the purpose and principles of each diet, the meal</td>
<td>A 631</td>
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A 631  Continued From page 90

pattern, the foods allowed and foods to avoid and
describes the nutritional adequacy and/or
inadequacy of each diet. The diet manual and
diets ordered by the hospital should mirror the
nutritional care provided by the hospital
(California Department of Public Health, 2013).

On 2/8/17 beginning at 11:32 a.m., the
Registered Dietitian RD 4 stated they used the
electronic version of the Nutrition Care Manual
from a professional organization. The RD 4
stated the most current version was on the
hospital intranet but she was not sure where to
locate it. Additionally the hospital also presented
an undated document titled "Therapeutic Diet
Details" that partially described the standardized
diets that were at the hospital. This document
had about 35 different diets on it. The hospital
provided a list of all the diets that can be ordered
in the electronic medical record and there was
approximately 54 diets not counting all of the
different calorie levels for the diabetic diet (11
different calorie levels). The undated document
did not provide a purpose, nutritional
adequacy/inadequacy of the diets nor did it
provide a meal pattern that was specific to the
hospitals' menu.

On 2/8/17 at 11:40 a.m., an joint observation with
RD 4 and a licensed nurse (LN 18) was
conducted regarding the electronic diet manual.
The LN 18 showed how to locate the Diet Manual
on the hospital intranet. When asked how she
was able to look up how to order a diet or how to
print out information regarding the diets on there
she stated she was not sure. LN 18 stated she
knew how to order diets on the electronic medical
record and if a patient needed information then
**A 631** Continued From page 91

she would print out education material from a tab regarding discharge instructions.

On 2/8/17 at 11:50 a.m., the RD 4 tried to print out the dysphagia diet from the electronic Diet Manual. The information was more about the diagnosis of dysphagia and treatment for it including the dysphagia outcome and severity scale. RD 4 stated she was not sure how to get information about the diet and what kind of diet was provided by the hospital for dysphagia. RD 4 stated maybe RD 5 would have more information about that. An example is that the hospital also has a Enhanced Protein diet and this diet was not in the electronic diet manual. They could provide a high calorie, high protein nutrition therapy which was a component of education material intended to be given to patients, rather than specific for the hospitals' delivery of patient care and diet they provided. RD 4 stated they provide an enhanced protein diet and they would give one scoop of protein powder in a food item for each meal. This information was not found in the electronic diet manual.

On 2/9/17 at 10:15 a.m., an interview was conducted with RD 5 regarding the diet manual. The RD 5 stated they pay for 1 subscription for the hospital and was not sure how to access through the hospital intranet but could access under the site directly. RD 5 was able to find information regarding the Dysphagia Level 1 pureed diet which included the purpose, thickened and thin liquids, cooking and preparation tips, foods recommended and not recommended and a 1 day sample menu. The RD 5 stated maybe staff needed more
A 631 Continued From page 92

Information on how to locate this since it was in a
different area then where the electronic diet
manual was on the intranet. RD 5 was able to
pull out information regarding a consistent
carbohydrate diet however it was a component of
education material that was intended to be given
to patients; rather than specific for the hospitals'
delivery of patient care. RD 5 stated they have
more of a traditional calorie level diabetic diet
that they provide to the patients in the hospital.
Therefore the information in the Diet Manual was
not specific to the hospital diabetic diet. Another
example is that the hospital also has a Enhanced
Protein diet and this diet was not in the electronic
diet manual. They could provide a high calorie,
high protein nutrition therapy which was a
component of education material intended to be
given to patients, rather than specific for the
hospitals' delivery of patient care and diet they
provided.

A 655 482.30(c) SCOPE AND FREQUENCY OF
REVIEW

(1) The UR plan must provide for review for
Medicare and Medicaid patients with respect to
the medical necessity of--
   (i) Admissions to the institution;
   (ii) The duration of stays; and
   (iii) Professional services furnished including
drugs and biologicals.

(2) Review of admissions may be performed
before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this
section, reviews may be conducted on a sample
basis.
A 655 Continued From page 93

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in §412.80(a)(1)(ii) of this chapter.

This STANDARD is not met as evidenced by:

Based on facilities Utilization Review (UR) Plan review and interview, the facility failed to review for professional services furnished.

This failure placed patient's at risk of under use, overuse and untimely use of available health facilities and services.

Findings:

Facility policy and procedure titled, "Utilization Review Plan," dated 12/14, indicated in part, "The UR Committee shall establish processes to review Medicare and Medicaid patients with respect to the medical necessity of: Admissions; Duration of stay; and Professional services furnished including drugs and biological's."
A 655 Continued From page 94
During a concurrent UR committee minutes review from year 2015 and 2016, and interview with licensed nurse 3 (LN 3), on 2/9/17, at 12 p.m., LN 3 acknowledged that the facility UR committee does not review for professional services furnished, LN 3 stated, "Yes, we know we need to start doing this."

A 701 482.41(a) MAINTENANCE OF PHYSICAL PLANT
The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

This STANDARD is not met as evidenced by:
Based on observation, dietetic service staff interview and departmental document review, the hospital failed to ensure:

1. A well-defined disaster feeding plan that met patient nutritional parameters. Failure to ensure a disaster plan that could be readily implemented by staff and included foods that would likely be consumed by patients may result in further compromising the medical and nutritional status of patients and staff.

2. In addition based on record review and interview, the facility failed to maintain a safe environment in their anesthetizing locations. This was evidenced by the failure to ensure that their policy for maintaining relative humidity (RH) between 20% and 60% is compatible with the safety guidelines of equipment used in the OR. This was also evidenced by the failure to perform corrective actions when RH levels fell below 20%, even during surgeries. This affected four of
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

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<th>COMPLETION DATE</th>
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<td>A 701</td>
<td>Continued From page 95 four ORs and could result in the increased risk of a fire.</td>
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**Findings:**

1. On 2/7/17 beginning at 3:00 p.m., an observation and a concurrent review of the hospital's disaster preparedness plan for nutrition services was conducted with the Director of Dietary Services (DDS). In a concurrent interview he stated the plan was for three days and for 60 plus patients and staff. The DDS stated he was not sure of the exact number but it was more than 60. The DDS stated the three day menu consisted of freeze dried foods and frozen foods. The DDS stated he was not sure if the stand by kitchen (where the disaster foods were stored) would be operable during a disaster. The hospital has a licensed bed count of 60.

Review of the hospital's document titled, Section 4, Disaster Planning, Preparedness and Execution, Safety Manual dated 2016, showed the community depends on Lompoc Healthcare District to be available when a Disaster occurs, to lead the care for themselves and their families. It showed the hospital may also be a convenient location for rescuer relief, supplying meals and shelter.

A review of the departmental document titled, "Emergency Kitchen Inventory," dated 1/17, revealed the food items on hand for the three day emergency menu. It showed different food items and how much was on hand. There was no par level or how much food on hand was needed.
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There was three cases of peanut butter on hand however there were no portion sizes for the peanut butter on the menu or no recipe to show how much peanut butter was needed for the peanut butter and jelly sandwich. Depending on the food item, they would have 72 servings on hand to 153 servings on hand. Review of the 3-day Emergency menu, updated 5/17/10, showed there was meat lasagna listed for one meal however there was stuffed cabbage listed on the inventory and observed in the freezer. A concurrent interview was conducted with the DDS and he stated the stuffed cabbage was in place for the meat lasagna. He also stated they had the freeze dried beans instead of the listed beef and bean chili that was on the menu. Further review showed there was bean salad. The DDS stated they would use the small red beans for the salad. He was not sure if there was a recipe for that on the can. He acknowledged they needed recipes for some of the menu items in the disaster binder in the stand by kitchen. Further review of the 3-day Emergency menu, showed there was a tuna salad sandwich listed however there was no recipe or serving sizes. It is unclear how much tuna salad is needed on hand. It showed there was pineapple tidbits and applesauce but no portion sizes on the menu. A concurrent interview with the DDS, he stated they are now using the freeze dried pineapple and apple cans. Further review of the 3-day Emergency menu showed a pureed diet. It showed to use canned puree foods or regular items if able to blenderize. A concurrent interview was conducted with the DDS regarding if they would be able to blenderize foods since they had no pureed canned foods on hand. He was not sure. The
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050110

(X2) MULTIPLE CONSTRUCTION
A. BUILDING _____________________________
B. WING _____________________________

(X3) DATE SURVEY COMPLETED
02/10/2017

NAME OF PROVIDER OR SUPPLIER
LOMPOC VALLEY MEDICAL CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE
1515 E OCEAN AVENUE
LOMPOC, CA 93436

(X4) ID PREFIX TAG
SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

(X5) COMPLETION DATE

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A 701 Continued From page 97
DDS also acknowledged they had no recipes on hand if they could blenderize the foods. There was one #8 scoop (1/2 cup) as a utensil in the stand by kitchen however there was no indication on the menu that a #8 scoop was needed for the specific items on the menu.

On 2/9/17 at 10:30 a.m. an interview was conducted with Registered Dietitian (RD) 5 regarding the Emergency Menu. RD 5 stated she was not familiar with the Emergency menu and was not involved in reviewing that. RD 5 did not think they ever did a nutrition analysis of the emergency menu. Review of the folders of the nutritional analysis, showed there was no emergency menu that was analyzed.

19.1.1.3 General. The provisions of Chapter 4, General, shall apply.

4.5.8 Maintenance. Whenever or wherever any device, equipment, system, condition, arrangement, level of protection, or any other feature is required for compliance with the provisions of this Code, such device, equipment, system, condition, arrangement, level of protection, or other feature shall thereafter be maintained, unless the Code exempts such maintenance.

4.6.1.1 The authority having jurisdiction shall determine whether the provisions of this Code are met.

4.6.1.2 Any requirements that are essential for the safety of building occupants and that are not specifically provided for by this Code shall be
A 701 Continued From page 98 determined by the authority having jurisdiction.

On 2/20/15, CMS released memorandum S&C: 15-27-Hospital, CAH & ASC titled "Potential Adverse Impact of Lower Relative Humidity (RH) in Operating Rooms (ORs)." The memorandum stated:

"The Centers for Medicare & Medicaid Services (CMS) previously issued a categorical waiver via S&C 13-25-LSC & ASC, which permits hospitals and CAHs with new and existing ventilation systems supplying anesthetizing locations to operate with a RH level of 20 % or greater in accordance with American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 170, Ventilation of Health Care Facilities." It also stated "Subsequently it has come to light that an RH level <30% is not compatible with the instructions for use (IFUs) for some sterile supplies and electro-medical equipment used in operating rooms" and "The CMS expects hospitals, CAHs and ASCs to follow the current IFUs for supplies and equipment used in their ORs. Failure to adhere to the IFUs must be cited, even if the facility has opted to use the categorical waiver of the LSC RH requirements. Citations would fall under §482.41(c)(2) for hospitals, §485.623(b)(1), for CAHs, and §415.44(a)(1) for ASCs."

During record review with staff from 2/7/17 to 2/10/17, policies for maintaining the RH in the OR, the OR temperature/humidity logs, and the OR equipment IFUs were requested.

1a. At 10:56 a.m., on 2/7/17, Maint 3 showed the...
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

A. BUILDING _____________________________
B. WING _____________________________

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(2) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:
050110

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

050110 02/10/2017

STREET ADDRESS, CITY, STATE, ZIP CODE
1515 E OCEAN AVENUE
LOMPOC, CA  93436

SUMMARY STATEMENT OF DEFICIENCIES
(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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A 701 centralized computer system used by the Facilities Department to monitor temperature and humidity levels in the ORs. According to the system, the set point and ambient temperature for OR 1 was 63 degrees Fahrenheit, 5 degrees below the low point of the 68 to 72 degrees Fahrenheit range allowed per the facility's policy. Ambient temperature in OR 2 was 65 degrees Fahrenheit and was 65.5 degrees Fahrenheit in OR 3. There was a legend on the screen that indicated certain colors can show different conditions of the system like red for "alarm" and orange for "fault." No alarm conditions were exhibited.

During an interview at 10:57 a.m., on 2/7/17, Maint 3 confirmed that the temperature was out of range. He stated that the surgeons always complain about the ORs being too hot. He said he was unsure if any alarm set points have been programmed into the system.

During an interview at 3:36 p.m., on 2/7/17, Maint 3 stated that he records the temperature and humidity values into a paper log once a day anytime between 7 a.m. to 3:30 p.m. but usually in the mornings. He stated that the HVAC vendor confirmed that the system had a capability to exhibit alarms when the OR conditions were out of range but no alarm set points have been programmed into their system yet.

2a. During an interview at 3:41 p.m., on 2/7/17, LN 13 stated that maintenance are responsible for checking temperature and humidity in the OR but she does check the thermostat for temperature. She did not mention checking the
### Summary Statement of Deficiencies

Each deficiency must be preceded by full regulatory or LSC identifying information.

#### 3. The facility failed to ensure that the OR conditions were monitored in a reliable manner.

Per the handwritten humidity and temperature logs created by maintenance, the humidity levels fell below 20% and no corrective actions were recorded:

- **a. OR 1:** The humidity was recorded as 17% on 12/18/16 and no corrective action was recorded.
- **b. OR 2:** The humidity was recorded as 18.6% on 12/18/16 and no corrective action was recorded.
- **c. OR 3:** The humidity was recorded as 18.5% on 12/3/16, on 12/17/16 where the humidity was recorded as 19.2% on 12/17/16, and the humidity was recorded as 12.7% on 12/18/16. No corrective actions were recorded.
- **d. OR 3:** The humidity was recorded as 18.4% on 11/30/16 and a note next to the date stated "notified OR. Check in 24 hours" but no follow up

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**Note:**

- **A 701 Continued From page 100**
- **A 701**
<table>
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<td>PREFIX</td>
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<td>DEFICIENCY)</td>
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<tr>
<td>A 701</td>
<td>Continued From page 101 humidity reading or specific corrective action was recorded. It was unclear if the note was regarding the temperature or humidity since both were out of range.</td>
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<tr>
<td>e. OR 3: the humidity was recorded as 17.4% on 10/8/16 and a note next to the date stated &quot;notified OR. Check in 24 hours. Turn temperature up&quot; but no follow up humidity reading was recorded. It was unclear if the note was regarding temperature or humidity levels since they were both out of range.</td>
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<td>f. OR 4: the humidity was recorded as 18% on 12/3/16 and as 15.4% on 12/18/16. No corrective actions were recorded for both dates.</td>
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<td>4. At 8:37 a.m., on 12/9/17, maintenance staff showed electronic graphs of previous humidity trends in the ORs from their computer system. Cross-reference of the graphs and the surgery schedule showed that the humidity levels fell below 20% during surgeries as listed below:</td>
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<td>a. OR 1, 12/20/16: the graph showed that the humidity was 19.63% at 10:40 a.m. and dipped to 5.5% by 2:20 p.m. The surgery schedule showed that a procedure was performed in OR 1 that day.</td>
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<tr>
<td>b. OR 2, 12/20/16: the graph showed that the humidity was 18.75% at 6:57 a.m., gradually dipped to 5% by 1:05 p.m., and increased to 19.46% by 3:32 p.m. The humidity was below 20% for approximately 8 hours and the surgery schedule showed that there were two procedures performed in OR 2 that day.</td>
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A 701 Continued From page 102

c. OR 2, 12/19/16: the graph showed that the humidity was 16.73% at 7:38 a.m. and went down to 15.43% at 12:32 p.m. The surgery schedule showed that there were three procedures performed in OR 2 that day with start times of 7:30 a.m., 9:00 a.m., and 10:00 a.m.

d. OR 2, 11/18/16: the graph showed that the humidity was 19.81% at 11:41 a.m. and dropped to 14.36% by 2:08 p.m. The surgery schedule showed that there was a procedure performed with the start time of 11:30 a.m. that day.

e. OR 3, 12/19/16: the graph showed that the humidity had gradually decreased from the day before down to 13.72% at 6:34 a.m. and increased to 19.69% by 12:40 p.m. The surgery schedule showed that there were three procedures performed in OR 3 that day starting at 7:00 a.m., 7:15 a.m., and 8:30 a.m.

f. OR 4, 12/19/16, the graph showed that the humidity was 17.32% at 9:00 a.m. and continued to go in an out of range until the next day. The surgery schedule showed that there were seven procedures performed in OR 4 on 12/19/16 starting at 7:00 a.m. to after 1:00 p.m.

g. OR 4, 11/18/16, the graph showed that the humidity was 19.5% at 9:57 a.m. and decreased to 10.75% by 12:24 p.m. The surgery schedule showed that there was a procedure performed in OR 4 that began at 9:30 a.m.

Surgeries were performed when humidity levels were below 20%.

5. At 11:20 a.m., on 2/8/17, the "Temperature and
### A 701

**Summary Statement of Deficiencies**

Continued From page 103

Humidity in the Perioperative Department" policy dated 9/16 was provided. Under the "Background" heading, the policy stated that generally acceptable relative humidity levels were between 30 to 60 % but that new standards are in process to decrease the relative humidity to 20%. The background information section also included this sentence "older equipment may not be optimal at that level." Under the "Procedure" section, the policy stated that maintenance were to note the humidity levels daily and the acceptable perimeters were 20 - 60%. Part C of the "Procedure" section stated that the facility would follow the "manufacturer's instructions for use relating to relative humidity and temperature."

During an interview at 12:39 a.m., on 2/8/17, Maint 1 stated that he would need to track down the IFUs for the equipment used in the ORs. He stated that the facility is going by the 20 to 60% humidity range.

At 3:20 p.m., on 2/9/17, the IFU for the lithotripsy laser machine indicated that its operating conditions included an RH level from 30 to 60%.

IFUs for the anesthesia machines and the laser were provided but none were provided for the rest of the equipment.

The facility failed to review all the equipment IFUs, in accordance with CMS guidelines and their policy, before implementing an OR humidity range of 20 to 60%.

6. At 12:00 p.m., on 2/8/17, the temperature and humidity logs kept by maintenance staff were
A 701

Continued From page 104 provided for the four ORs. Review of the last three months showed days where the humidity fell below 30% which may not have been compatible with all equipment IFUs:

a. OR 1: the humidity fell below 30% during 4 of 31 days in January 2017, during 8 of 31 days in December 2016, and during 2 of 31 days in October 2016.

b. OR 2: the humidity fell below 30% during 7 of 31 days in January 2017, during 8 of 31 days in December 2016, during 1 of 30 days in November 2016, and during 2 of 31 days in October 2016.

c. OR 3: the humidity fell below 30% during 14 of 31 days in January 2017, during 17 of 31 days in December 2016, during 8 of 30 days in November 2016, and during 5 of 31 days in October 2016.

d. OR 4: the humidity fell below 30% during 8 of 31 days in January 2017 and during 14 of 31 days of December 2016.

The facility failed to ensure that humidity levels less than 30% were compatible with the equipment used in the OR.

6. During an interview with the chief nursing executive (LN 2) on 2/9/17, at 9:30 a.m., LN 2 was asked if she was aware that the OR humidity and temperatures may have been a problematic? LN 2 stated, "No, that's managed by maintenance." LN 2 was asked if she was aware that the nursing OR staff was not aware of what the correct humidity and temperatures...
### Statement of Deficiencies and Plan of Correction

**Name of Provider or Supplier:** Lompoc Valley Medical Center  
**Street Address, City, State, Zip Code:** 1515 E Ocean Avenue, Lompoc, CA 93436

<table>
<thead>
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<td>A 701</td>
<td>Continued From page 105 parameters should be, LN 2 stated, &quot;No, I wasn't aware of this, we check the patients temps during surgery so they should not get hypothermia (when the body loses heat faster than it produces heat, causing a dangerously low body temperature).&quot;Asked if LN 2 was aware that the computerized system to alert staff when the temperatures and humidity was outside of the regulatory parameters had not been set-up, LN2 stated, &quot;I would not know about that.&quot;</td>
<td>A 701</td>
<td>A 703 482.41(a)(2) Emergency Gas and Water</td>
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<tr>
<td>A 703</td>
<td>There must be facilities for emergency gas and water supply. This STANDARD is not met as evidenced by: Based on observation, review of the mass disaster preparedness plan and staff interview, the hospital failed ensure there was a system to provide water to the hospital patients and staff during a disaster situation. Failure to have a detailed written plan and supplies needed to distribute water during a disaster may result in compromising both patients and staff. Findings: On 2/9/17 at 11:38 a.m., an observation was conducted with Maint 1 regarding the hospital's disaster water supply. 875 gallons of water were observed in three large containers. Maint 1 stated they would plan for three days and he thought one gallon per person per day. A concurrent interview was conducted with Maint 1 at this time. When asked how the water would be distributed from the tank, Maint 1 stated by a hose. When asked if there was a hose he stated no but they could go grab a garden hose.</td>
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<td>A 703</td>
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somewhere. Maint 1 stated he did not know it would need to be a food grade safe hose. When asked what they would put the water in, he stated that was a good question. Maint 1 stated they did not have any detail on the specifics of getting the water out and being able to distribute it to the patients and staff. Maint 1 stated they did not have any specific policy or procedure in writing on disaster water but he would include that in his binder of other materials for disaster.

On 2/9/17 at 11:55 a.m., an interview was conducted with the Safety Officer. The Safety Officer stated he was unsure what the number of people they planned for during a disaster. The Safety Officer stated he would expect the Director of Dietary Services (DDS) to have that information.

On 2/7/17 at 3:00 p.m., an interview was conducted with the DDS regarding Disaster food. The DDS stated that the plan was for 60 plus people. The hospital has a licensed bed count of 60 people. The DDS was not sure how many staff and visitors they were also planning for during a disaster.

Review of the hospital's disaster planning, preparedness and execution dated 2016, did not specify how many people or any specifics about water during a disaster.

Review of the hospital policy and procedure titled Emergency Management under the Nutritional Services Department, dated 2/08, showed the Nutritional Services director is responsible for securing food and water inventories with the assistance of the Safety and Security Officer.
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<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tr>
<td>A 703</td>
<td>Continued From page 107</td>
<td>A 703</td>
<td>Review of the Inventory list showed disaster water supply consisted of six large containers (three water heaters and three storage tanks) equaling a total of 2075 gallons of palatable drinking water which is enough for 200 people, one gallon per person per day for 10 days.</td>
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<tr>
<td>A 747</td>
<td>482.42 INFECTION CONTROL</td>
<td>A 747</td>
<td>The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases. This CONDITION is not met as evidenced by: Based on observations, interviews and record review, the facility failed to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases and conduct an active program for the prevention, control and investigation of infections and communicable diseases and these failures place the patient population at risk for hospital acquired infections when: 1. When an Infection Control Construction Risk Assessment was not performed prior to a construction project in operating room number 4 (A-749). 2. Standards of surgical attire were not followed in the operating room (A-749). 3. Instruments were discolored and etched, conditions that interfere with sterilization (A-749).</td>
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| A 747         | Continued From page 108  
4. Endoscope handles were labeled with peelable tape creating a barrier on the handle that prevented high level disinfection of the instrument (A-749).  
5. The ongoing need for Foley catheters in a patient was not assessed on a daily basis according to current requirements (A-749).  
6. Personal protective equipment was not available in the emergency department decontamination area (A-749).  
7. Environmental temperatures of three operating rooms and the sterile supply room were out of required range and no interventions took place to bring them into acceptable range (A-749).  
8. The lack of an effective system to monitor time/temperature control of nine of nine previously cooked foods capable of producing foodborne illness. (A-749)  
9. Storage of foods capable of supporting bacterial growth associated with foodborne illness in an under counter refrigerator in the café. (A-749)  
10. The lack of an effective system to monitor the temperature of foods capable of supporting bacterial growth associated with foodborne illness in the salad bar in the cafe. (A-749).  
11. The lack of gloves being worn when handling ready to eat foods. (A-749)  
12. Failure to maintain sanitation buckets at | A 747 |
### SUMMARY STATEMENT OF DEFICIENCIES

<table>
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<th>A 747 Continued From page 109 appropriate concentration levels. (A-749)</th>
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The cumulative effects of these systemic problems resulted in the hospital's inability to provide a sanitary environment and systems to avoid the sources and transmission of infections, and the prevention of food borne illnesses, in accordance with the statutorily mandated Conditions of Participation for Infection Control Services.

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The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

This STANDARD is not met as evidenced by:

- Based on observation, interview and documentation review, the facility failed to develop a system for controlling infections and communicable diseases of patients when:
  1. When an Infection Control Construction Risk Assessment was not performed prior to a construction project in operating room number 4.
  2. Standards of surgical attire were not followed in the operating room.
  3. Instruments were discolored and etched, conditions that interfere with sterilization.
  4. The ongoing need for Foley catheters in a patient was not assessed on a daily basis according to current requirements.
### SUMMARY STATEMENT OF DEFICIENCIES

(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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5. Personal protective equipment was not available in the emergency department decontamination area.

6. Environmental temperatures of three operating rooms and the sterile supply room were out of required range and no interventions took place to bring them into acceptable range.

7. Endoscope handles were labeled with peelable tape creating a barrier on the handle that prevented high level disinfection of the instrument.

8. The lack of an effective system to monitor time/temperature control of nine of nine previously cooked foods capable of producing foodborne illness.

9. The lack of gloves being worn when handling ready to eat foods.

10. The lack of an effective system to monitor the temperature of foods capable of supporting bacterial growth associated with foodborne illness in the salad bar in the cafe.

11. Storage of foods capable of supporting bacterial growth associated with foodborne illness in an under counter refrigerator in the cafe.

12. Failure to maintain sanitation buckets at appropriate concentration levels.

These failures have the potential to cause infection and foodborne illnesses that could
A 749 Continued From page 111

negatively impact a patient's health status affecting the hospital licensed bed count of 60.

Findings:

1. On February 6, 2017 at 11:40 a.m., during a tour of perioperative services and an interview with infection control preventionist (ICP) and a licensed nurse (LN 12), they stated that the facility uses the Centers for Disease Prevention and Control (CDC), the Association for Professionals in Infection Prevention and Epidemiology (APIC) the Society for Healthcare Epidemiology of America (SHEA) and the Association of peri-Operative Nurses (AORN) standards as the nationally recognized guidelines for the Infection Control Program of the facility. During the tour, operating room 4 was observed to have access blocked with a large plastic wall barrier. LN 12 stated that the floor was being replaced and the construction began on February 3, 2017. There was no visible Infection Control Construction Risk Assessment (ICCRA) posted outside of the construction site.

On February 8, 2017, in an interview with ICP, she stated that she was not notified of the construction project until February 6, 2017 and the ICCRA was not begun until February 6th and it was not posted at the worksite until February 8, 2017.

The facility policy entitled Construction and Renovation Policy and Procedures, dated September 2015, was reviewed on February 8, 2017 at 2:30 p.m., the policy states that before any construction on-site begins, the contractor's onsite management team shall attend a
A 749 Continued From page 112

mandatory meeting held by the...infection control authorities for instruction about precautions to be taken. In addition, before the project gets under way, perform Infection Control Construction Risk Assessment to define the scope of the activities and the need for barrier measures... [furthermore a] permit must be displayed at the entrance to work area during entire construction period.

According to AORN Standards of peri-Operative Nursing Practice, Guideline for a Safe Environment of Care, Part 2 (2017): during renovation and construction in the close vicinity of an occupied health care facility, measures for preventing environmental contamination should be established, maintained, and monitored by perioperative team members and the infection preventionist in accordance with applicable state regulations and the ongoing risk assessment.

2. On February 6, 2017 at 11:40 a.m., during an interview, a licensed nurse (LN 12) stated that the facility has adopted the Association of peri-Operative Nurses (AORN) Guidelines for Perioperative Practice for the infection control program.

On February 6, 2017 at 12 p.m., MD 1 was observed during surgery in operating room 3, to be wearing a surgical mask that did not cover heavy growth of facial hair on either side of his face mask extending to his sideburns. This was validated by LN 12.

On February 8, 2017 at 2:30 p.m., the policy entitled Perioperative Services: Quality Improvement/Infection Control, dated November 2016, was reviewed. The policy states that all
head and facial hair should be covered when in
the ...restricted areas of the surgical suite (the
operating room is a restricted area).

According to AORN Standards of peri-Operative
Nursing Practice, Surgical Attire (2017):
Personnel entering the semi-restricted and
restricted areas should cover the head, hair,
ears, and facial hair. Hair and skin can harbor
to bacteria that can be dispersed into the
environment.

3. On February 6, 2017 at 11:40 a.m., during an
interview, a licensed nurse (LN 12) stated that
the facility has adopted the Association of
peri-Operative Nurses (AORN) Guidelines for
Perioperative Practice for the infection control
program.

On February 6, 2017 at 12:30 p.m., during a tour
of the sterile instrument preparation room, two
surgical instrument trays (one major and one
minor instrument tray) were opened and
inspected. Of 40 instruments examined, two
instruments had discolored distal ends and five
instruments had etched surfaces just below the
handle.

According to AORN Standards of peri-Operative
Nursing Practice, Cleaning and Care of Surgical
Instruments (2017): Inspection of instruments
before processing may minimize the risk of
damaged, nonfunctioning, or incorrectly
functioning instruments being used in patient
care. Tissue and debris can become lodged in
crevices, box locks, lumens, and other areas of
instruments. Items should be inspected and
evaluated for cleanliness; corrosion, pitting,
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burrs, nicks, cracks; wear and chipping of inserts and plating. Defective instruments should be identified, removed from service, and repaired or discarded.*

4. On February 6, 2017 at 11:40 a.m., during an interview, a licensed nurse (LN 12) stated that the facility has adopted the Association of peri-Operative Nurses (AORN) Guidelines for Perioperative Practice for the infection control program.

On February 6, 2017 at 1 p.m., during a tour of the endoscopy processing areas, the cabinet containing the endoscopes (an instrument used to visualize the gastrointestinal tract) was examined. Two Olympus® endoscopes (identification numbers H180 and 0160) had tape on the handle in the shape of a number for identification purposes (#8 and #3 respectively). An operating room technician (ORT 1) verified that the tape remained on the handle during the entire high level disinfection process. The tape covered some of the surface area of the handle. ORT 1 stated that the facility used an automated endoscopy reprocessing machine for high level disinfection of the endoscopes.

According to AORN Standards of peri-Operative Nursing Practice, Guideline for Processing Flexible Endoscopes (2017): Contact of all surfaces of the endoscope with processing solutions is necessary to achieve effective processing [high level disinfection] ...If endoscopes are not adequately cleaned, the disinfection or sterilization process can fail and increase the possibility for transmission of infectious microorganisms from one patient to
Continued From page 115

Flexible endoscopes and accessories should be positioned within the mechanical processor in a manner that ensures contact of the processing solutions with all surfaces of the endoscope.

5. On February 7, 2017 at 9:30 a.m., during a review three medical records of patients with Foley catheters (a tube inserted into the bladder to drain urine in a collection bag), one (Patient 2) out of three did not have appropriate documentation in the medical record for ongoing need of a Foley. For Patient 2, the medical record stated the reason to continue the Foley catheter was "monitor urinary output in a critically ill patient". The patient was on a medical surgical unit and had a doctor's order for discharge. ICP, ICP 2 and LN 18 verified that this patient did not meet criteria according to facility policy for the ongoing need of a Foley catheter.

The facility policy entitled Urinary Catheter: Indications for Use of an Indwelling Urinary Catheter Policy, dated September 2016, was reviewed on February 8, 2017 at 2:30 p.m. The policy states: "Nurses will assess the patients need for an indwelling urinary catheter daily. Indications for continuing a urinary catheter will be clearly documented in the patient record. If the patient meets criteria for no longer requiring a urinary catheter, the physician will be notified and an order from the physician to discontinue the urinary catheter will be requested."

6. During an observation on February 7, 2017, at 11:05 a.m., of the dirty utility room in the Emergency Department, there was no personal
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

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<th>PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:</th>
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#### SUMMARY STATEMENT OF DEFICIENCIES

1. **A 749** Continued From page 116 protective equipment (PPE) available in the room for staff to use when handling soiled instruments.

   **During an interview with the emergency department director (LN 6), on February 7, 2017, at 11:05 a.m., LN 6 confirmed that there was no PPE available in the dirty utility room for staff use, and that there should be.**

   The record review of the facility policy and procedure titled "Cleaning, Disinfection, Storage of Patient Care Equipment and Instrument Trays" , dated December 2016, indicated that personnel who decontaminate instruments must wear PPE: gloves, liquid-resistant gown, eye protection, and a surgical mask if risk of splash or aerosols is present.

   The record review of the facility policy and procedure titled "Emergency Services- Infection Prevention and Control", dated November 2016, indicated that staff shall use PPE when handling soiled items.

   7. On February 6, 2017 at 11:40 a.m., during an interview, a licensed nurse (LN 12) stated that the facility has adopted the Association of peri-Operative Nurses (AORN) Guidelines for Perioperative Practice for the infection control program.

   On February 7, 2017 at 3:30 p.m., during a tour of operating room 2, the temperature was noted to be 66° F. This was verified by LN 12. When asked who recorded the temperature and adjusted it within required ranges she said that it was recorded centrally by Plant Maintenance staff and they adjust the temperature when it is
A 749 Continued From page 117 out of range.

On February 8, 2017 at 2:30 p.m. the January 2017 Temperature and Humidity Tracking Log, kept by Plant Operations, for Operating Room 2 was reviewed. Out of 31 calendar days, 25 days were recorded to be out of range. In the space on the form for documentation of "Actions Taken if Out of Range" there were no entries for any of the 25 days. In the next column entitled "Temperature or Humidity After Actions Taken" there was no documentation for any of the 25 days noted to be out of range. The bottom of the document stated that the temperature range is 68° F to 75° F. The printed instructions were: If temperature...[is] not within range notify surgery. Document the actions taken and then re-measure to assure that the affected parameter is within the acceptable range.

According to AORN Standards of peri-Operative Nursing Practice, Guideline for a Safe Environment of Care, Part 2 (2017): “The health care organization should create and implement a systematic process for monitoring HVAC performance parameters and a mechanism for resolving variances. Personnel who identify an unintentional variance in the predetermined HVAC system parameters should report the variance according to the health care organization’s policy and procedures. Rapid communication between affected and responsible personnel can help facilitate resolution of the variance. The temperature range in a restricted area should be 68° F to 75° F.”.

8. According to the Center for Disease Control
A 749 Continued From page 118

and Prevention (CDC) report for 1993-1997, "Surveillance for Food-borne Disease Outbreaks - United States," identified the most significant factors to food borne illness. Improper cooking and improper holding temperatures are two of several categories identified as contributing factors directly relate to food safety concerns.

The Federal Food and Drug Administration (FDA) refers to improper cooling and holding temperature activities that directly relate to food safety concerns Food-borne illness risk factors.

Potentially Hazardous Foods (PHF) are those that are capable of supporting bacterial growth associated with foodborne illness. PHF’s require time and temperature control through all phases including receiving, storage and food production. It would be the standard to ensure that hot PHF’s are consistently monitored and cooled from 135°F (degrees Fahrenheit) to 70°F within 2 hours and to 41°F or less in an additional 4 hours, a maximum total of 6 hours. Similarly, foods that are prepared from room temperature ingredients shall be monitored to ensure temperatures decrease to 41°F or below within 4 hours of preparation (Federal Food Code 2013).

During the initial tour of the kitchen in the hospital on 2/7/17 starting at 10:55 a.m., the following items were observed in the walk-in refrigerator:
- cooked pork dated 2/6/17 with a temperature of 38.4°F;
- cooked scrambled eggs and cooked potatoes labeled as breakfast dated 2/6 and use by 2/11 with temperatures of 35.9°F and 36.5°F respectively;
- cheese sauce dated 2/5 and use by 2/10 with a temperature of 43.5°F;
- marinara sauce dated 2/5 and use by 2/10 with a temperature of 44.9°F.

A 749
A 749 Continued From page 119

Continued From page 119

temperature of 36.5°F. A concurrent interview was conducted with the Director of Dietary Services (DDS) when he stated they make the sauces at the hospital and they were not from a can. The DDS stated foods are good for 5 days once it is opened or prepared.

In the dairy walk-in refrigerator on 2/7/17 at 11:20 a.m., a container of tuna salad was observed dated 2/6 with a use by date of 2/11 with a temperature of 36.5°F.

On 2/7/17 at 11:40 a.m., in the cafe under the grill there were reach-in refrigerator drawers that were 30°F. In one of the drawers the following items were observed: cooked turkey burger patties dated 2/6 that were 42.8°F, cooked veggie burger patties dated 2/6 with a temperature of 43.3°F, and cooked hamburger patties dated 2/6 with a temperature of 42.9°F. A concurrent interview was conducted with the DDS, he stated that the food items would stay in the reach in drawers throughout the day and night. The DDS stated these foods are precooked in advance.

On 2/7/17 at 12:45 p.m. an interview was conducted with Cook 1 and Cook 2 regarding cool down procedures for foods cooked in advance. Cook 1 stated they cook quite a few items in advance then would cool down and write in a log. Cook 1 stated he would start the cooling process when the PM cook finishes it when his shift is over. When asked what the cooling procedure was, he stated in 2 hours the food should be 70 degrees F then they have 4 more hours to get the food to 41 degrees F or less. Cook 1 stated they would sometimes keep...
A 749 Continued From page 120
breakfast leftovers then he would use that to put in breakfast burritos and served another day. Cook 1 said they only put hot items on the log. When asked about the food items dated on 2/6 in the walk-in refrigerator, Cook 1 looked at the log and no items were dated 2/6. Cook 1 stated they had a new cook over the weekend and he must not have put any food items on the log so when he came to work on Monday he thought the date was the 4th instead of the 6th. Cook 1 stated the pork loin was on the log just with the incorrect date. Cook 2 was asked what she knew about the cool down procedures. Cook 2 stated she just takes one temperature and writes the temperature on the log. Cook 2 stated she usually takes the temperature around 2:30-3:30 but doesn't always put the time next to the temperature. Cook 2 stated she does not go back to verify if the food ever reaches 41 degrees F. Cook 2 stated she was not aware that the food had to get to 41 degrees F in 4 hours. Regarding the pork loin on the log, Cook 2 stated she thought the temperature was taken around 3 p.m..

During the survey it was noted that PHFs were not being monitored for safe cooling to 41 degrees Fahrenheit (F) or less within 4 hours when prepared from ingredients at room temperature.

According to the 2013 FDA Food Code, potentially hazardous food (time/temperature control for safety food) shall be cooled within 4 hours to 41 degrees F or less if prepared from ingredients at ambient (room) temperature, such as reconstituted foods and canned tuna.
A 749 Continued From page 121

On 2/7/17 at 3:45 p.m., an interview was conducted with the DDS regarding cool down. The DDS stated after looking at the log that foods needed to get to 70 degrees in 2 hours and 41 in 4 hours. He stated they put all protein foods on the log. He stated the cheese sauce, leftovers and all protein foods should be monitored on the log. The DDS stated the check marks on the cooling log meant that they ended up serving the food in the cafe before it was done cooling. He acknowledged that the other items did not reach 41°F or less. The DDS acknowledged he had not really reviewed the log to see if temperatures reached 41°F. The DDS stated he was unsure when the last time he gave an in-service of cooling foods but stated it was not done in the last year. The DDS acknowledged that they did not monitor cooling of ambient food items like tuna salad.

On 2/8/17 at 9:59 a.m., an observation of the reach-in drawers under the grill in the cafe was conducted. The hamburger patty's dated 2/6 were 43.9°F, and the turkey burger patty's dated 2/6 were 42.6°F. In a concurrent interview with the DDS, he stated he would throw out those items and the other items would be placed in the walk-in refrigerator. He stated if those drawers can not keep temperatures below 40 then he would not be able to store items in there. The DDS stated they do not monitor the items in there on the cafe daily food temp log, mostly just monitor the hot food items. The DDS acknowledged he did not have a cool down policy and the food storage policy did not address all types of food items and what their temperatures needed to be at. The DDS stated all refrigerator food items needed to be less than
A 749 Continued From page 122

40 degrees.

Review of the untitled Cooling Log dated 1/30 through 2/7 showed, pork loin dated "2/6" at 1100 it was 167°F, 1:00 it was 66°F then there was no time on last column but the temperature showed 50°F. There was potato bar dated "2/6" and showed at 11:15 it was 180°F, at 1:15 it was 70°F then the last column showed the temperature was 58°F with no time on it. Further review of the log dated from 9/29/16 until 2/7/17, showed that 131 out of 141 food items did not reach 41°F or less.

Review of the hospital document titled cool down log instructions, undated, showed all protein items listed on this log need to be cooled to 70 degrees within the first two hours and then cooled to 41 degrees within the next four hours. It showed that for any reason the items are not cooled to 41 degrees within six hours then all of the product must be discarded. The form did not say what to do with protein items that started out as ambient temperatures.

Review of the hospital policy titled Infection Control Food Storage revised 1/3/17, showed produce and dairy food items to be stored in the refrigerator and maintained between 35 to 40 degrees F. The policy does not show any temperatures for meat items to be stored at.

On 2/8/17 at 12:45 p.m. an interview was conducted with the DDS regarding his role as the director. The DDS stated he is supposed to have in-services with the staff every month but due to lack of staffing it has not happened as often. The DDS stated he had a staff meeting with the
A 749 Continued From page 123

department last month dated 1/12/17 and the
time before that was 4/7/16. The DDS stated
they do have a new position for a Food Service
Technician but it has not been filled. The DDS
stated he does not do any sanitation audits of his
department but the Infection Control
Preventionist does them from time to time.

On 2/8/17 at 4:19 p.m. an interview was
conducted with the Infection Control
Preventionist (ICP) regarding her role over the
Food Service Department. The ICP stated she
does quarterly audits on all departments
including the kitchen. The ICP stated she will
plan with the DDS when she will come and
conduct her audit since this is more efficient way
to have him with her. She stated at times she will
do some unannounced rounds of the kitchen but
she will not use a form for those.

On 2/9/17 at 8:25 a.m., an interview was
conducted with the ICP regarding her last
quarterly audit. The ICP stated this form was the
form that was at the hospital when she started so
she just uses it. A concurrent review of the Food
and Nutrition Sanitation Inspection Form dated
12/16/16 was conducted. It showed that under
temperature control item #1 that "Yes", Foods
are maintained below 41 degrees F or above 135
degrees F at all times and in all serving areas.
Under comments it showed "per interview with
the director of dietary". Under #10 it showed that
"Yes" rapid cooling procedure is used for all
perishable foods in shallow pans, monitored from
135 to 70 degrees F, then 70 to 41 degrees F in
4 hours. The total cooling process from 135 to 41
does not exceed 6 hours. Under comments it
showed, "per interview with the director of
Continued From page 124

dietary”. When asked, the ICP stated she would interview the director and look at the logs. When the surveyor showed her the cooling logs dated 12/11 through 12/16/16, it showed nine of nine times the last cooling temperature was between 50 and 62 degrees F. The ICP stated that if the temperature was between 70 and 41 degrees F then it was okay. The Inspection Form also showed the salad bar in service temperature is less than 41 degrees F. There was nothing written under the comment section. The ICP stated she would look at the logs but would not check the temperatures of foods herself, she mostly would ask the DDS about the items and look at logs. The ICP stated she did not have any specific training on infection control in food service. If she had questions about things she stated she would ask the Director of Dietary or the Registered Dietitian at the hospital or contact the County Department of Public Health. The ICP stated she would appreciate having more training in food service.

9. According to the Food and Drug Administration (FDA) Food Code 2013, Section 3-301.11 Preventing Contamination from Hands, "...food employees may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment.”

Ready to eat foods that are packaged onsite present a greater risk of cross contamination. In order to have active managerial control over personal hygiene and cross-contamination, certain control measures must be implemented in all phases of the operation including prevention.
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<td>A 749</td>
<td>Continued From page 125</td>
<td>of cross contamination of ready-to-eat food or clean and sanitized food-contact surfaces with soiled cutting boards, utensils, aprons, etc., (USDA Food Code 2013 Annex).</td>
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A 749 Continued From page 126 day.

Review of the hospital's Cafe Daily Food Temperature log, showed temperatures of two food items (imitation crab and 1000 island dressing) were dated 2/3/17, tuna salad and ranch dressing dated 2/2/17 and cottage cheese dated 2/1/17. There was no time of the items. There was no temperatures of cold food items for 2/7/17.

On 2/9/17 at 8:25 a.m., an interview was conducted with the ICP regarding her last quarterly audit. The ICP stated this form was the form that was at the hospital when she started so she just uses it. A concurrent review of the Food and Nutrition Sanitation Inspection Form dated 12/16/16 was conducted. It showed the salad bar in service temperature is less than 41 degrees F. There was nothing written under the comment section. The ICP stated she would look at the logs but would not check the temperatures of foods herself, she mostly would ask the DDS about the items and look at logs. The ICP stated she did not have any specific training on infection control in food service. If she had questions about things she stated she would ask the Director of Dietary or the Registered Dietitian at the hospital or contact the County Department of Public Health. The ICP stated she would appreciate having more training in food service.

12. On 2/8/17 at 9:22 a.m., Cook 1 was observed wiping down the counter and sink with a cloth from the red sanitizer bucket. A concurrent interview was conducted with the Cook 1 about the red sanitizer bucket. The Cook 1 stated everyone had their own red bucket and they were
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<td>A 749</td>
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supposed to change the bucket every two hours. Cook 1 checked the concentration level of the sanitizer bucket at this time and it was less than 200 parts per million (ppm). Cook 1 held the strip in the sanitizer bucket for 21 seconds. Cook 1 and the DDS stated it was not at the correct ppm since it needed to be at least 200 ppm. Cook 1 stated it needed to be changed again since it was last changed at 7 a.m.. When asked how long the strip has to be in the sanitizer solution he stated he gives it 15 seconds even though it says only 10 seconds on the manufacturer's label. The sanitizer bucket was changed and the strip still was not reading 200 ppm. When asked the DDS and Cook 1 if the temperature of the solution had to be a certain temperature, the DDS stated room temperature. The DDS stated he was not aware it had to be a specific temperature. The temperature of the solution was 67.4 degrees F. The DDS brought out another type of testing strip for the Quaternary Ammonium Solution which did not need the solution to be a certain temperature and that read 400 ppm. At this time, the DDS stated they would start using the new testing strip to test the red sanitation buckets.

Review of the pHydron Papers QT-40 label, showed to dip paper in Quaternary solution for 10 seconds. Don't shake and compare colors at once. It showed the testing solution should be at 75 degrees F.