STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	390100	A. BLDG: 00 B. WING:	12/06/2023

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
LANCASTER GENERAL HOSPITAL, THE STATE LICENSE NUMBER: 120801	555 NORTH DUKE STREET LANCASTER, PA 17602

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P 0000	INITIAL COMMENT This report is the result of an unannounced onsite special monitoring investigation completed on December 6, 2023, at Lancaster General Hospital. It was determined that the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Hospitals, 28 PA Code, Part IV, Subparts A and B, November 1987, as amended June 1998.	P 0000		
P 0361		P 0361		

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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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P 0361	Continued from page 1 103.22 (b)(16) IMPLEMENTATION 103.22 (16) The patient has the right to expect good management techniques to be implemented within the hospital considering effective use of the time of the patient and to avoid the personal discomfort of the patient. This REGULATION is not met as evidenced by:	P 0361	Action: Executive responsible for oversight of Plan of Correction to ensure the safety of surgical patient Responsible Party: Chief Operating Officer; Chief Physician Executive; President of Medical Staff Completion Date: 11/21/23 Action: Pre-Patient Arrival Time Out initiated for dual verification that instruments are available and in appropriate condition Responsible Party: Senior Director, Perioperative Services Completion Date: 11/21/23 Action: Initiated Bi-weekly multi-disciplinary leadership team meetings Responsible Party: Chief Operating Officer Completion Date: 11/21/23	Completion Date: **01/31/2024** Status: **APPROVED** Date: **01/03/2024**

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P 0361	Continued from page 2	P 0361	Action: Request submitted to travel agency for additional OR and Sterile Processing Department (SPD) staff Responsible Party: Associate Chief Human Resources Officer Completion Date: 11/21/23 Action: Started a monitoring tool to ensure all instruments are available and condition ready for use. Responsible Party: Director, Performance Improvement, Senior Director, Perioperative Services Completion Date: 11/21/23 Action: Market adjustment to assist with retention and recruitment Responsible Party: Associate Chief Human Resources Officer Completion Date: 11/26/23 Action: Quality observations of SPD Standard Work	

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P 0361	Continued from page 3	P 0361	Responsible Party: Vice President, Quality and Regulatory Affairs Completion Date: 11/29/23 Action: Initiated automated instrumentation quality reports for distribution to OR Leaders daily Responsible Party: Interim Manager, SPD Completion Date: 12/8/23 Action: Plan of Correction discussed at Board Quality Committee meeting Responsible Party: Chief Operating Officer Completion Date: 12/11/23 Action: Communication initiated with Vendors via email setting firm expectations for loaner tray arrival/removal/storage Responsible Party: Interim Manager,	

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P 0361	Continued from page 4	P 0361	SPD Completion Date: 12/19/23 Action: Purchased silicone corner protectors for SPD trays Responsible Party: Interim Manager, SPD Completion Date: 12/21/23 Action: Assessment of volume of instruments conducted and needed instruments ordered Responsible Party: Interim Manager, SPD Completion Date: 12/21/23 Action: Executive Team perioperative rounding Responsible Party: Chief Operating Officer Completion Date: 12/27/23	

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P 0361	Continued from page 5	P 0361	Action: Interim SPD manager hired Responsible Party: Senior Director, Perioperative Services Completion Date: 1/8/24 Action: Contracted organization to assess and implement quality improvement initiatives in SPD Responsible Party: Senior Director, Perioperative Services Completion Date: 1/8/24 Action: SPD staff re-educated on contaminated instrument preparation and instrument processing standard work checklists Responsible Party: Senior Director, Perioperative Services Completion Date: 1/31/24	

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P 0361	Continued from page 6 Based on review of facility documents, medical records (MR), and staff interviews (EMP), it was determined the facility failed to provide appropriate sterile equipment supplies to prevent delay of care for six out of six MR's reviewed (MR1, MR2, MR3, MR4, MR5 and MR6). Findings Include: Review of facility policy "Patient Bill of Rights" last revised October 2017, revealed "The following Statement of The Patient's Rights and Responsibilities is endorsed by the Administration and staff of this facility and applies to all patients ... 13. Right to good hospital management - Patients have the right to expect good management techniques to be implemented within LGH. They may expect every effort will be made to avoid unnecessary delay and, when possible, to avoid undue personal discomfort. ..." Review of facility document note for MR1 entered by EMP4 on September 8, 2023, at 10:57 AM	P 0361		

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P 0361	Continued from page 7 revealed "Patient scheduled for Total ankle replacement. When setting up OR [operating room], it was discovered that the loaner instrumentation trays were never processed by SPD [Sterile Processing Department]. Case cancelled." Review of facility document note for MR2 entered by EMP5 on November 10, 2023, at 12:52 PM revealed "Holes were found in 4 trays due to no protective foam placed on corners of trays. 6 trays didn't have protective corners. Surgeon was notified. Surgeon stated that he didn't want the trays to be flashed. Surgeon and [instrument] sales rep discuss instrumentation options as there were no sterile back up trays ... This also resulted in an approximate 40-minute delay in case start." Review of facility document note for MR3 entered by EMP6 on November 16, 2023, at 12:52 PM revealed "OR Team had all of the equipment for their case this morning. However, another room needed it due to contamination issues. Rep brought in needed trays at 10:45 AM. Rep reported Sterile	P 0361		

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P 0361	Continued from page 8 Processing was saving a washer for their instruments. However, the washer autoloaded other instruments delaying washing/sterilization. Case was supposed to begin at 12:45 PM. There was a two-hour delay in receiving the trays. Two out of four trays were wet. The surgeon opted to flash items needed to proceed with case. Charge nurse was aware and in communication with Sterile Processing the entire time. The surgeon decided to keep the patient overnight in observation status due to the case running later. Initial plan was for the patient to be discharged home during the day." Review of MR4 Progress Note entered on November 14, 2023, at 2:23 PM by EMP2 revealed "No sterile total shoulder tray available to do procedure. Also hole in implant tray wrapping - unsterile. Not safe to proceed with flashed trays for joint arthroplasty. Will postpone surgery. Discussed with patient, upset but agreeable. Sling immobilizer dispensed as patient already received RIGHT interscalene block."	P 0361		

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P 0361	Continued from page 9 Review of MR5 Progress Note entered by EMP3 on November 16, 2023, at 10:47 AM revealed "Upon preparing for the case, we found a hole in the retractor set. There was also 2 broaching sets that were opened and both were contaminated with bone on the broaching trial sets. We had no further sterile backup instrumentation. Procedure cancelled." Review of facility document note for MR6 entered by EMP11 on November 16, 2023, at 10:49 AM revealed "the patient received the nerve block, after that it was identified that a crucial tray needed for surgery was contaminated and the case almost needed to be aborted after nerve blockade. A different vendor was able to accommodate the implants/trays. Significant delay to surgery occurred." Interview with EMP2 on November 21, 2023, EMP2 confirmed surgery was delayed as noted above for MR3 and cancelled for MR4 as noted above.	P 0361		

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P 0361	Continued from page 10 Interview with EMP1 on November 21, 2023, EMP1 confirmed all information above and documents submitted are complete and accurate.	P 0361		
P 4605		P 4605		

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P 4605	Continued from page 11 146.1 (b)(3) PRINCIPLE 146.1 (b) The multidisciplinary committee described in section (a) shall do the following: (3) Develop, evaluate, and revise on a continuing basis the procedures and techniques for meeting established sanitation and asepsis standards. This REGULATION is not met as evidenced by:	P 4605	Action: Executive responsible for oversight of Plan of Correction to ensure the safety of surgical patients Responsible Party: Chief Operating Officer; Chief Physician Executive and President of the Medical Staff Completion Date: 11/21/23 Action: Postings on OR doors to demonstrate revised surgical attire policy Responsible Party: Senior Director, Perioperative Services Completion Date: 12/29/23 Action: Standard of Work for Cleaning, Packaging, and Sterilization of Instruments in the Clinic Setting, Standard of Work for Handling and Assembling Trays/Peel Pouches in Prep and Pack, and Immediate-Use Steam Sterilization and Flash Pack Policies updated and staff re-educated	Completion Date: **02/15/2024** Status: **APPROVED** Date: **01/03/2024**

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P 4605	Continued from page 12	P 4605	Responsible Party: Senior Director, Perioperative Services Completion Date: 1/31/24 Action: Surgical Attire Policy revised and staff educated to revision Responsible Party: Senior Director, Perioperative Services Completion Date: 1/31/24 Action: Monitor compliance to surgical attire policy Responsible Party: Senior Director, Perioperative Services Completion Date: 2/15/24	

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P 4605	Continued from page 13 Based on review of facility documents, observations, and staff interviews (EMP), it was determined the facility failed to follow adopted policies and procedures to ensure sterile instruments and supplies are maintained properly. Findings include: Review of facilities document "Standard of Work for Cleaning, Packaging, and Sterilization of Instruments in the Clinic Setting" last update December 16, 2021, revealed "Purpose: To provide staff with standard instructions for proper reprocessing of reusable instruments ... Expected Outcome Instrument will be properly packaged and sealed for sterilization. Internal indicators provide the end user with proof of sterilization." Review of facilities document "Standard of Work for Handling and Assembling Trays/Peel Pouches in Prep and Pack" last reviewed October 2022, revealed "Purpose: To provide staff with standard instructions for proper handling, assembling and	P 4605		

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P 4605	Continued from page 14 packaging trays/peel pouches ... Major Steps Final set/peel pouch check: Inspect peel pouch/rigid container thoroughly. Things to look for: 1. Ensure the correct amount of integrators are in the correct locations of the tray/peel pouch. 2. Cleanliness of container/peel pouch. 3. Inspect container and lid/peel pouch for any damage or holes. 4. Inspect the rubber seal on the lid to ensure there and no breaks, cracks, or missing pieces which could compromise the seal of the container ... Expected outcomes: Items will be neat, organized, and functional resulting in the OR [Operating Room] staff having the best quality instruments available that are clean, sterile, and safe to use on the patient. Proper care and handling from Sterile Processing Department [SPD] staff will lead to less complications during the procedure." Review of facilities policy "Immediate-Use Steam Sterilization and Flash Pak" last revised April 2021, revealed "Procedure General Considerations: ... 2. It is not appropriate to use immediate-use sterilization in these circumstances: a. Surgical	P 4605		

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P 4605	Continued from page 15 Implants except in a documented emergency situation b. Insufficient inventory c. Borrowed instruments or surgeon's personal instruments. ..." On November 21, 2023, review of facility "SPD Debrief Tool "noted by EMP13 on August 21, 2023, revealed "In OR6 case 15, No bottom filters for Versys Acetabular Reamers 4, no other sets sterile had to flash." On November 21, 2023, review of facility "SPD Debrief Tool" noted by EMP14 on August 22, 2023, revealed "Autoclave was used to flash item, but nothing was documented on flash paper. Flash Pak was not stored in proper upside-down position to allow to dry." On November 21, 2023, review of facility "SPD Debrief Tool" noted by EMP15 on September 27, 2023, revealed "In OR 3 there was no indicator in Depuy ACTIS Core Case 6." On November 21, 2023, review of facility "SPD Debrief Tool "noted by EMP12 on September 28, 2023, revealed "In OR 2 there was no indicator in Laparoscopic pan."	P 4605		

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P 4605	Continued from page 16 On November 21, 2023, review of facility "SPD Debrief Tool "noted EMP17 on October 24, 2023, revealed " In OR 1 case cart 18 had holes in wrapper for Synthes Large External Fixator 1 and 2." On November 21, 2023, review of facility "SPD Debrief Tool "noted by EMP18 on October 25, 2023, revealed " In OR 8 case cart 46 had holes in wrapper for Spotlight Microdiscectomy case 2 and Spotlight Port Case 1." On November 21, 2023, review of facility "SPD Debrief Tool "noted by EMP16 on October 25, 2023, revealed "In OR 1 case cart 35 had holes in wrapper for Synthes Stardrive Locking Small Fragment Set 2." Review of facility document note for MR2 entered by EMP5 on November 10, 2023, at 12:52 pm revealed "Holes were found in 4 trays due to no protective foam placed on corners of trays. 6 trays didn't have protective corners." Review of facility document note for MR3 entered by EMP6 on November 16, 2023, at 12:52 pm revealed "OR Team had all of the equipment for	P 4605		

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P 4605	Continued from page 17 their case this morning. However, another room needed it due to contamination issues. Rep brought in needed trays at 10:45 am. Rep reported Sterile Processing was saving a washer for their instruments. However, the washer autoloaded other instruments delaying washing/sterilization. Case was supposed to being at 12:45 pm. There was a two-hour delay in receiving the trays. Two out of four trays were wet. The surgeon opted to flash items needed to proceed with case." Review of MR5 Progress Note entered by EMP3 on November 16, 2023, at 10:47 am revealed "Upon preparing for the case, we found a hole in the retractor set. There was also 2 broaching sets that were opened and both were contaminated with bone on the broaching trial sets. We had no further sterile backup instrumentation." Observation on November 21, 2023, in Ortho OR6 Versys Acetabular set 3 missing an indicator. Observation on November 21, 2023, in Main OR 4	P 4605		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	390100	A. BLDG: 00 B. WING:	12/06/2023

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
LANCASTER GENERAL HOSPITAL, THE STATE LICENSE NUMBER: 120801	555 NORTH DUKE STREET LANCASTER, PA 17602

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE	(X5) COMPLETE DATE
P 4605	Continued from page 18 a hole noted in basin set received from SPD. Interview with EMP19 on November 21, 2023, EMP19 confirmed the document information noted above is complete and accurate. Interview with EMP1 on November 21, 2023, EMP1 confirmed the observations noted above both occurred in the ORs. --- Based on review of facility documents, observations, and staff interview (EMP), it was determined the facility failed to follow adopted policies and procedures to minimize the opportunity for personnel to serve as a source of infection in the Operating Rooms (OR). Findings include: Review of facility policy "Surgical and Procedural Attire" last revised August 2023, revealed "Policy	P 4605		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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P 4605	Continued from page 19 Purpose: The purpose of this policy is to minimize the opportunity for operating room personnel to serve as a potential source of infection and to maintain aseptic conditions to safely carry out surgical procedures. Definitions: Restricted Area: include the rooms in which operative or other invasive procedures are performed (i.e., operating rooms, procedural suites) and where there are unwrapped sterile supplies (sterile core). The Sterile Processing Department (SPD) restricted areas include the Assembly Area, Autoclave Area, and Clean/Sterile Storage. Personnel in the restricted areas must wear surgical attire, head covering, facial hair covering, and masks at all times. Procedure:3. Don a surgical mask when entering restricted areas and at scrub sinks while others are scrubbing. a. A mask should cover both mouth and nose and be secured in a manner that prevents venting at the sides of the mask. b. Don a fresh mask before performing or assisting with each new procedure. c. Masks should be fully donned or doffed and may not be worn around neck between patient care episodes. ..."	P 4605		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	390100	A. BLDG: __00_____ B. WING: _____	12/06/2023

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
LANCASTER GENERAL HOSPITAL, THE STATE LICENSE NUMBER: 120801	555 NORTH DUKE STREET LANCASTER, PA 17602

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P 4605	Continued from page 20 During tour of OR Suite on November 21, 2023, observed EMP8 in Main OR4 without a mask on; EMP9 in Main OR4 without a mask on; EMP10 in Main OR5 without a mask on. Interview with EMP1 on November 21, 2023, EMP1 confirmed the above EMP's were without mask inside of the ORs.	P 4605		

Certified End Page

LANCASTER GENERAL HOSPITAL, THE

STATE LICENSE NUMBER: 120801

SURVEY EXIT DATE: 12/06/2023

I Certify This Document to be a True and Correct Statement of Deficiencies and Approved Facility Plan of Correction for the Above-Identified Facility Survey

Jeane Parisi
Deputy Secretary for Quality Assurance

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

pennsylvania
DEPARTMENT OF HEALTH

THIS IS A CERTIFICATION PAGE

PLEASE DO NOT DETACH

THIS PAGE IS NOW PART OF THIS SURVEY