

August 12, 2022

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Director, Sterile Processing and Material Management
Perioperative and Procedural Services
8794

**Subject: *Sterile Processing Department
Report 2022-15***

The final report for Sterile Processing Department 2022-15, is attached. We would like to thank all members of the department for their cooperation and assistance during the review.

Because we were able to reach agreement regarding management action plans in response to the audit recommendations, a formal response to the report is not requested. The findings included in this report will be added to our follow-up system. We will contact you at the appropriate time to evaluate the status of the management action plans.

UC wide policy requires that all draft reports be destroyed after the final report is issued. We also request that draft reports not be photocopied or otherwise redistributed.

Christa Perkins
Director
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Attachment

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UC San Diego

AUDIT & MANAGEMENT ADVISORY SERVICES

Sterile Processing Department
Report No. 2022-15
August 2022

FINAL REPORT

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I. EXECUTIVE SUMMARY

Audit & Management Advisory Services (AMAS) has completed a review of the Sterile Processing Department (SPD) at University of California San Diego Health (UCSDH) as part of the approved audit plan for Fiscal Year (FY) 2021-22. The objective of our review was to evaluate whether SPD internal controls provided reasonable assurance that financial results are accurately reported, operations are effective and efficient, and activities are compliant with relevant policies and procedures.

Based on our review, we concluded that the Sterile Processing Department internal controls could be improved to provide reasonable assurance that financial results are accurately reported, operations are effective and efficient, and activities are compliant with relevant policies and procedures.

The SPD team overall has been effective in performing the sterile processing procedures which includes decontamination, sterilization and assembly of instruments and instrument kits for all services supported by the operating rooms, based on the identified needs of the ORs, ancillary departments and clinics given the current available space and staffing resources.

However, during our review we noted that the current management team is facing challenges of managing capacity and workflow while ensuring instruments are processed timely and according to regulatory standards. Staffing changes and reorganization to meet location operational requirements in some cases also disrupts operational workflow. This appears to have resulted in inconsistent documentation and oversight to ensure that required daily equipment cleaning and inspection tasks are performed, and that an adequate number of instrument assembly audits are completed. SPD relies heavily on the use of Travelers for temporary employment to fill in staffing needs with gaps in lead and supervisor roles required to oversee the sterile processing workflow. Without backup personnel and additional resources, SPD's ability to manage and meet OR needs at current capacity is limited, and any increase in OR cases as UCSDH facility and services expand will likely amplify these challenges. We identified opportunities for improvement in the quality assurance process, as well as staff scheduling and work attendance, equipment management, and space utilization.

Management Action Plans to address our findings are as follows:

A. Quality Assurance

1. SPD temporarily redeployed the Manager and KOP supervisors to JMC to cover leadership needs and address operational issues until new supervisors are hired.
2. SPD is currently recruiting supervisors to fill in vacancies in leadership positions at all SPD locations.
3. SPD management will consider additional management strategies, such as requiring Manager(s) to review all lead and supervisor checklists and periodic verification of logs, to ensure quality assurance tasks are consistently performed and documented and any issues are addressed timely.
4. SPD management will ensure new and existing processes and policies are implemented at all locations for consistency, such as requiring a Lead Checklist at all locations, and ensuring all checklists are reviewed regularly by the Manager.
5. SPD management will evaluate current and future staffing and leadership requirements to meet operational needs near and long-term.
6. SPD management will coordinate with Health Human Resources (HHR) to identify and utilize appropriate management training and performance management oversight for employees appointed/promoted to leadership positions.

B. Staff Schedules and Work Attendance

1. SPD is in the process of implementing an online staff scheduling system. Supervisor training is scheduled to begin in July 2022.
2. SPD has implemented employee sign-in sheets for temporary employees to better track and verify attendance and time reported.
3. SPD is recruiting additional supervisors to help oversee staff schedule and attendance, and review timesheets for accuracy and compliance.
4. SPD is in the process of formalizing staff communication on overtime requirements, to ensure all employees are aware of it and allowed the opportunity to formally respond to accept a preauthorized overtime offer.
5. SPD management will regularly obtain and review timekeeping reports for late attendance to identify, implement and document required management actions for addressing non-compliance, and update personnel records as appropriate.
6. SPD management will implement a formal process to communicate and document preauthorization of overtime. In addition, SPD should regularly reconcile overtime hours reported to ensure overtime reported is preauthorized, approved and adequately supported, and that any issues are addressed timely.
7. SPD management will periodically review timesheets to ensure supervisor approval is obtained and that work hours reported were consistent with the staffing schedule.
8. SPD will ensure new processes are implemented across all SPD locations for consistency, and that new attendance logs are continuously maintained and reconciled with hours reported on timesheets.

C. Equipment Management

1. SPD will coordinate with Equipment Planning and Procurement to evaluate options that may be available for the unused VPRO sterilizer and other equipment for SPD use, regardless of the financial unit or project to which the cost is charged.
2. SPD management will periodically review Campus Asset Management System (CAMS) and Clinical Technology inventory records to verify all equipment listed is accounted for, and ensure records are complete and accurate. Discrepancies listed in **Attachment A** should be resolved.
3. SPD management will regularly review and reconcile equipment depreciation schedules with CAMS and Clinical Technology equipment inventory records to ensure the accuracy of depreciation costs charged to SPD financial units, and evaluate the need for replacement based on the frequency and cost of repairs and maintenance required on fully depreciated equipment.

D. Space Utilization

1. SPD management will coordinate with UCSDH leadership and vendors to evaluate appropriate action and/or space requirements for storage of unused loaner instruments and/or instrument trays.
2. SPD management, in coordination with Perioperative Services leadership, will identify a reasonable timeframe to store vendor-owned instruments in accordance with applicable policy, and, based on that determination, formalize a policy specifically governing the management and timely return of vendor loaner instruments and instrument trays.

Observations and related Management Actions Plan are described in greater detail in section V. of this report.

II. BACKGROUND

Audit & Management Advisory Services (AMAS) has completed a review of the Sterile Processing Department (SPD) at University of California San Diego Health (UCSDH) as part of the approved audit plan for Fiscal Year (FY) 2021-22. This report summarizes the results of our review.

SPD is a support department within UCSDH Perioperative and Procedural Services, which includes anesthesia, procedural and surgical services across all UCSDH locations. The types of support provided by SPD include, but are not limited to, the decontamination, sterilization, and assembly of instruments and instrument kits for all services supported by the operating rooms (OR)¹. SPD services are based on the identified needs of the ORs, ancillary departments² and clinics. SPD operates 24 per day, 7 days per week at Jacobs Medical Center (JMC) and Hillcrest Medical Center (HC) locations, 24 hours per day Mondays through Fridays at Koman Family Outpatient Pavilion (KOP), and at various times Mondays through Fridays at all other SPD locations, such as the Shiley Eye Institute (Shiley).

Reporting to the Chief Administrative Officer (CAO) for Perioperative and Procedural Services, the Director of Materials Management and SPD oversees overall SPD operations, with support from a Manager, an Assistant Manager, Supervisors and Floor Leads. Currently, only the JMC location has an Assistant Manager. All locations are assigned a supervisor and floor leads for each shift. Supervisors have ultimate 24-hour responsibility for their units' activities. The remainder of the staff following the SPD chain of command consist of sterile processing technicians who disinfect and eliminate the threat of germ contamination on instruments, tools and equipment by applying various means of appropriate sterilization and cleaning practices, while maintaining accurate records during sterile processing. SPD has a dedicated trainer/educator for permanent staff, and a separate trainer for temporary or traveling staff (Travelers).

SPD staff members are assigned responsibilities based upon educational preparation, applicable certification guidelines including scope of practice, regulations, and an assessment of current competence. SPD staff are certified in Inpatient BART (Basic Resuscitation Training) and all SPD technicians are trained and competent in sterile processing techniques in accordance with Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI). In order to provide support to the OR clinical team, ancillary departments and clinics, staffing levels are kept at adequate levels to support patient care. SPD hires temporary help to meet staffing requirements.

SPD support services are delivered in accordance with the goals, policies, and procedures of UCSDH, The Joint Commission (TJC) standards, California Department of Health (CDPH) and Title XXII requirements. Standards of care are performed in accordance with AAMI, ANSI, and Association of PeriOperative Registered Nurses (AORN).

SPD also works closely with UCSDH Infection Control since SPD is the first step in infection prevention for patients in UCSDH ORs. UCSDH Infection Prevention Control Environment (IPCE) and Environment of Care (EOC) perform regular rounds in SPD to ensure compliance with policy and standards. SPD follows AAMI standards, and staff competencies are closely monitored and reviewed annually. Sterility Quality

¹ OR Scope of Practice includes the provision of surgical services and perioperative support to patients requiring elective and emergency surgery.

²Ancillary departments and clinic locations include Hillcrest, La Jolla, Hillcrest Outpatient Pavilion, Lewis Family Medicine, La Jolla Family Medicine, La Jolla Dermatology, Lifesharing, Scripps Ranch, and Chancellor Park.

Assurance Reports are submitted to Infection Prevention and Control Environment quarterly. SPD equipment is regularly diagnosed to monitor pass/fail rate due to power, steam outage and operator error, tests are repeated and passed at point of use, and instrumentations are reprocessed during diagnostic failures. The second quarter Sterility Assurance Report for the period ended December 31, 2021 indicated an average pass rate of 96% for all equipment monitored and tested, and is included below.

	JMC (P/F)	Hillcrest (P/F)	KOP/Shiley (P/F)
Steris System 1E Total loads PASSED / FAILED % (Failed Loads Passed at Point of Use)	87.54% / 12.46%	93.69% / 6.31%	97.13% / 2.87%
Steris System 1E Diagnostic Tests PASSED / FAILED % (Failed diagnostics Passed at Point of Use)	91.23% / 8.77%	91.76% / 8.24%	100% / 0%
Sterrad and V-Pro Total Loads PASSED / FAILED % (Failed loads passed at point of use) (JMC Location uses both Sterrad and V-Pro. All other locations only has Sterrad)	97.80% / 2.20%	95.37% / 4.63%	98.10% / 1.90%
Sterrad Biological Testing PASSED / FAILED % (Failed loads passed at point of use)	99.28% / 0.72%	98.30% / 1.70%	97.10% / 2.90%
VPro Leak PASSED / FAILED % (Failed loads passed at point of use)	100% / 0%	N/A	N/A
VPro Biological PASSED / FAILED % (Failed loads passed at point of use)	97.86% / 2.14%	N/A	N/A
Pre-Vac Steam Total Loads PASSED / FAILED % (Failed loads passed at point of use)	99.65% / 0.35%	98.02% / 1.98%	99.43% / 0.57%
Pre-Vac Steam Leak Testing PASSED / FAILED % (Failed Leak Test passed at point of use)	93.59% / 6.41%	76.67% / 23.33%	94.83% / 5.17%
Pre-Vac Steam Dart Testing PASSED / FAILED % (Failed Leak Test passed at point of use)	100% / 0%	99.64% / 0.36%	99.32% / 0.68%
Pre-Vac Steam Biological Testing PASSED / FAILED % (Failed loads passed at point of use)	99.82% / 0.18%	99.89% / 0.11%	99.86% / 0.14%
<small>All diagnostics, DART, LEAK, and BI failures are due to power, steam outage and operator error. Tests were repeated and passed at point of use. Instrumentation were reprocessed.</small>			

Source: SPD Executive Summary on Sterility Assurance Report (SAR) October to December 2021

SPD also coordinates with Clinical Technology (formerly Biomedical Equipment Services (Biomed)) in managing equipment inventory, including repairs and maintenance, as well as with Equipment Planning for managing and identifying capital asset requirements.

Ongoing Capacity and Infrastructure Projects

SPD management has initiated several projects to improve and address space and capacity issues based on recommendations of outside consultants and the results of regulatory surveys. These projects include:

- Jacobs Medical Center SPD space expansion – a project plan was approved and initiated for space expansion by utilizing unused space on the lower level across from the JMC SPD.
- Hillcrest Medical Center SPD space expansion – a project requisition was approved in 2020 and is underway for space expansion by utilizing improved space for the Same-Day Surgery unit by adding deionized water and replacing a sink that meets regulatory requirements for SPD use.
- Hillcrest Outpatient Pavilion – a project design for SPD space was vetted by UCSDH leadership, with direct input from the SPD leadership team.

- Shiley Eye Institute SPD renovation – construction is underway with an estimated completion date of July-August 2022, which will allow space that meets regulatory requirements for SPD use from a clean to dirty workflow, as well as temperature and humidity guidelines.
- Koman Family Outpatient Pavilion – a project request was submitted to change the sinks to height-adjustable to address a Gastrointestinal (GI) ergonomic concern, as KOP SPD shares their decontamination space with GI three days per week. KOP SPD currently shares the entire space with Shiley OR daily (since Shiley SPD has been closed since 2018).
- Offsite SPD – a proposal was submitted to establish an off-site sterile processing space that will allow the SPD to support ambulatory locations off-site.

Specific SPD locations (JMC in La Jolla, HC in Hillcrest, and KOP in La Jolla) and operating costs are assigned to individual cost centers or financial units. SPD processes for Shiley are largely managed at KOP. The SPD cost center for Shiley was deactivated and financial activities are currently incorporated into Shiley OR. The SPD budget and operational costs flex with OR volume. JMC SPD supports 22 ORs, and also receives/processes instruments from up to 30-40 outside clinics daily. HC SPD currently supports 11 ORs which is expected to increase to 17 with HC expansion.

SPD leadership works with Finance in managing and reviewing financial reports. According to the UCSDH Profit/Loss Statements for the Fiscal Year (FY) ended June 30, 2021, SPD cost centers and financial units reported total operating expenses of \$8.4 million, equivalent to \$699K per month, which is a 9% unfavorable budget variance of \$681K, and is detailed below in *Table 1*. For FY 2021-2022, as of March 31, 2022, SPD had total operating expenses of \$7.3 million, equivalent to \$809K per month, which is a 18% unfavorable budget variance of \$1.1 million, and is detailed below in *Table 2*. Salaries and benefits make up 80% (78% in FY21) of total expenses, with 77 FTEs (73.9 in FY21) including contractual labor of 12.4 FTE (8.5 in FY21).

Table 1

SPD Financial Units	FY2021 Budget	FY2021 Actual	% Variance
JMC 4200152	\$4,444,711	\$4,815,903	(8%)
HC 4200712	\$2,007,259	\$2,206,700	(9%)
KOP 4200326	\$1,260,203	\$1,370,370	(9%)
Total Operating Expense	\$7,712,173	\$8,392,973	(9%)

Table 2

SPD Financial Units	FYTD March 2022 Budget	FYTD March 2022 Actual	Variance
JMC 4200152	\$3,492,229	\$4,399,991	(26%)
HC 4200712	\$1,655,615	\$1,779,424	(7%)
KOP 4200326	\$1,039,763	\$1,103,105	(6%)
Total Operating Expense	\$6,187,607	\$7,282,520	(18%)

III. AUDIT OBJECTIVE, SCOPE, AND PROCEDURES

The objective of our review was to evaluate whether SPD internal controls provided reasonable assurance that financial results are accurately reported, operations are effective and efficient, and activities are compliant with relevant policies and procedures. In order to achieve our objective, we performed the following:

- Reviewed the SPD organizational chart, and other available information through its website, including cost centers/financial units, policies and procedures, and available documents;
- Reviewed:
 - Applicable federal, state and other regulations and requirements relating to sterile processing;
 - Applicable UC and UCSDH policies;
 - SPD Financial statements, budget and variance reports for the FY ended June 30, 2021 and FYTD March 2022;
- Interviewed:
 - Director of Materials Management and SPD;
 - SPD Manager and Assistant Manager; and
 - Selected SPD personnel;
- Performed walkthrough of SPD facilities and adjacent spaces at JMC and HC;
- Evaluated a judgmental sample of:
 - Payroll reports and timekeeping records for selected SPD personnel for FY 2021-2022;
 - Non-compensation expenses including temporary employment, equipment repairs & maintenance, other purchased services and supplies;
 - Equipment Cleaning and Instrument Assembly Audit logs and documentation of monitoring practices for JMC, HC and KOP Sterile Processing units;
 - Selected capital assets and equipment listed in Campus Asset Management System (CAMS), and Clinical Technology inventory records as of May 2022;
- Examined a sample of invoices and supporting documentation for workflow and expenses, including equipment purchases, lease, repairs and maintenance and contracted labor (Travelers) for FY2021-2022 for JMC, HC and KOP Sterile Processing financial units; and
- Consulted with the following: Equipment Planning, Clinical Technology, Infection Prevention and Clinical Epidemiology (IPCE), Environment of Care (EOC), Procurement, Finance, Accounting, Payroll, and Facilities Planning - Core Services Business Administration.

Our review did not include units supported by SPD and other Perioperative Support Services.

IV. CONCLUSION

Based on our review, we concluded that the Sterile Processing Department internal controls could be improved to provide reasonable assurance that financial results are accurately reported, operations are effective and efficient, and activities are compliant with relevant policies and procedures.

The SPD team overall has been effective in performing the sterile processing procedures which includes decontamination, sterilization and assembly of instruments and instrument kits for all services supported by the operating rooms, based on the identified needs of the ORs, ancillary departments and clinics given the current available space and staffing resources. SPD also monitors and reviews instrument concerns

due to various reasons including incorrect or missing instruments and presence of bioburden³, to address issues and minimize OR delays. Lost instruments are usually charged to the OR units, and in some cases, replacement instruments or parts are charged to SPD⁴. SPD is also in the process of implementing a new instrument tracking system called Sterile Processing Microsystem Instrument Tracking Software (SPM) to allow integration with Epic, as well as automated and improved tracking and documentation of instruments processed. SPD has also initiated several projects to address capacity and space constraints.

However, during our review we noted that the current management team is facing challenges of managing capacity and workflow while ensuring instruments are processed timely and according to regulatory standards. Staffing changes and reorganization to meet location operational requirements in some cases also disrupts operational workflow. This appears to have resulted in inconsistent documentation and oversight to ensure that required daily equipment cleaning and inspection tasks are performed, and that an adequate number of instrument assembly audits are completed. SPD relies heavily on the use of Travelers for temporary employment to fill in staffing needs with gaps in lead and supervisor roles required to oversee the sterile processing workflow. SPD has spent \$1.4 million as of March 2022 (\$878K in FY2021) on contractual labor, which has approximately doubled in a period of one year, and already at an unfavorable 351% budget variance as of March 2022. Without backup personnel and additional resources, SPD’s ability to manage and meet OR needs at current capacity is limited, and any increase in OR cases as UCSDH facility and services expand will likely amplify these challenges.

We also noted that SPD relies heavily on Clinical Technology in managing equipment inventory. However, we noted a lack of accuracy and completeness in inventory records maintained as well as the repairs log. We identified opportunities for improvement in the quality assurance process, as well as staff scheduling and work attendance, equipment management, and space utilization. These observations are discussed in greater detail in the balance of this report.

V. OBSERVATIONS REQUIRING MANAGEMENT ACTION

A.	Quality Assurance
The process for monitoring and ensuring compliance for equipment cleaning and instrument assembly was not consistently performed and documented, and instrument assembly audits are not consistently performed.	
Risk Statement/Effect	
Inconsistent performance and documentation of quality assurance could result in operational failure, and non-compliance with IFU requirements, policy and regulatory standards for sterile processing.	
Management Action Plans	
A.1	SPD temporarily redeployed the Manager and KOP supervisors to JMC to cover leadership needs and address operational issues until new supervisors are hired.

³ Bioburden is the degree of microbial contamination or microbial load; the number of microorganisms contaminating an object.

⁴ The FYTD March 2022 variance report indicated \$156K in medical instruments charged to SPD (\$93K for JMC or a 145% unfavorable budget variance, \$36K for HC or a 17% unfavorable variance, and \$26K for KOP or a 92% unfavorable variance).

A.2	SPD is currently recruiting supervisors to fill in vacancies in leadership positions at all SPD locations.
A.3	SPD management will consider additional management strategies, such as requiring Manager(s) to review all lead and supervisor checklists and periodic verification of logs, to ensure quality assurance tasks are consistently performed and documented and any issues are addressed timely.
A.4	SPD management will ensure new and existing processes and policies are implemented at all locations for consistency, such as requiring a Lead Checklist at all locations, and ensuring all checklists are reviewed regularly by the Manager.
A.5	SPD management will evaluate current and future staffing and leadership requirements to meet operational needs near and long-term.
A.6	SPD management will coordinate with Health Human Resources (HHR) to identify and utilize appropriate management training and performance management oversight for employees appointed/promoted to leadership positions.

A. Quality Assurance – Detailed Discussion

Equipment Cleaning Logs

SPD technicians disinfect and eliminate the threat of germ contamination on tools and equipment by applying various means of sterilization and cleaning practices. Technicians operate the steam autoclaves that sterilize instruments and are responsible for maintaining accurate records. All SPD staff are responsible for cleaning the sterilizers/disinfectors using up-to-date manufacturer’s instructions for use (IFU), and documenting this at daily and weekly intervals. A cleaning schedule is posted by the SPD Lead Technician who is responsible for monitoring compliance. Professional cleaning of the chamber is performed on a bi-annual basis (or as needed). SPD established processes for monitoring and testing the cleaning efficacy of the decontamination process for instruments and items decontaminated by the automated washer-sterilizers/disinfectors. Daily quality assurance testing is performed by a designated SPD technician, whereby daily cleaning and inspection of the washer/disinfector and washer tray table conveyer system is conducted, as well as weekly cleaning and inspection of the washer/disinfector, and documentation of review results and work performed in the SPD Equipment Cleaning Log, as well as communicating any issues with supervisors to ensure required action is initiated and followed through.

To validate the effectiveness of this process, we reviewed daily checklists completed by supervisors and floor leads to verify work completion, inspection/testing and documentation of monitoring and testing results. We noted several gaps in all months for FY 2022 through March at all locations for supervisor checklists. We also noted several gaps in the JMC floor Lead Checklist, and there was no checklist for floor leads at HC and KOP. SPD leadership indicated that the Lead Checklist is only required at JMC. We also noted that in some cases, monitoring/testing was not completed based on the information logged by the supervisors and leads. To verify documentation of work completion for sterilizers / disinfectors cleaning, we reviewed daily equipment cleaning logs for four randomly selected dates during the third quarter of the fiscal year, using dates when supervisors completed their checklist. However, we also noted gaps in those logs at JMC. These gaps in documentation of work completion are summarized in *Table 3*.

Table 3

SPD Documentation	# Days Tested	# of Days Compliant		
		JMC 4200152	HC 4200712	KOP 4200326
Supervisor Checklist	4	1	0	0
Lead Checklist	4	4*	Not required	Not required
Daily Equipment Cleaning Log	4	3	4	3**

*Task was marked N/A on checklist

**Location was closed on one of the dates tested

Instrument Assembly Audits

SPD staff are also responsible for ensuring that all instruments maintain integrity and are functioning properly prior to packaging for sterilization. Each instrument goes through visual inspection and testing according to manufacturer's IFU before and after processing and that any issues are reported to the SPD Lead or Supervisor to initiate repair, re-cleaning and/or processing as necessary. SPD policy and procedures provide guidance and methods of inspection, visualization, and validation of the cleaning process. Supervisors are also required to perform and complete a sterile processing instrument assembly audit on a daily basis, by selecting at least two sets of instruments per shift for audit. Supervisors also document completion of this task in the Supervisor Checklist log maintained in iShare⁵. To evaluate the effectiveness of this process, we reviewed supervisor checklists for JMC and HC locations to verify compliance, and noted gaps in the dates where a checklist was completed. In cases where a checklist was completed, we also noted gaps in the dates when instrument assembly audits were performed. For those audits completed, we also noted non-compliance on completing the required number of instrument sets for audit. We also randomly selected four days during the third quarter of the fiscal year to verify documentation of instrument assembly audits. However, we noted that no audits were completed for the four dates reviewed for JMC, HC and KOP locations. These gaps in completion and documentation of work completion based on sample reviewed are summarized in *Table 4*.

Table 4

SPD Documentation	# Days Tested	# of Days Compliant		
		JMC 4200152	HC 4200712	KOP 4200326
Supervisor Checklist	4	1*	0	0
Lead Checklist	4	Not required	Not required	Not required
Instrument Assembly Audits	4	0	0	0

*Task was marked "No" (i.e., Two Daily Audits Not Completed)

SPD leadership indicated that these gaps were due to management issues at JMC and leadership shortage in all locations. However, SPD management should consider new workflow management strategies to improve compliance and monitoring and consider requiring a Lead Checklist at all locations for consistency. Also, SPD management should ensure all checklists are reviewed regularly by the Manager to verify all required tasks and documentation are complete, and issues, if any, are addressed in a timely manner. To address management issues, the SPD Director has reassigned the Manager and KOP supervisors to temporarily oversee processes at JMC, however, this creates a leadership void in other locations from where the supervisor was reassigned. SPD is also in the process of recruitment to fill in current vacancies in supervisor positions at JMC and expects to hire these new employees in the first

⁵ iShare is an online document repository used to retain departmental / organizational documentation.

quarter of the new fiscal year 2023. SPD management should further evaluate current and future staffing and leadership requirements to ensure they will satisfy operational needs, and coordinate with HHR to identify and utilize appropriate management training and other tools for employees appointed / promoted to leadership positions for effective management of work and personnel.

B.	Staff Schedules and Work Attendance
<p>Timesheets were not consistently reviewed and verified to ensure hours reported by employees are accurate, overtime is authorized, and that non-compliance, if any, is addressed timely per policy. In addition, staffing schedules were not consistently updated to ensure accurate references for staff attendance.</p>	
Risk Statement/Effect	
<p>Lack of consistency and timeliness in reviewing employee attendance records and updating staffing schedules increases the risk of non-compliance, misstated expense and fraud. This could also result in staffing confusion and inefficiencies brought about by inaccurate time reporting and staffing schedules.</p>	
Management Action Plans	
B.1	SPD is in the process of implementing an online staff scheduling system. Supervisor training is scheduled to begin in July 2022.
B.2	SPD has implemented employee sign-in sheets for temporary employees to better track and verify attendance and time reported.
B.3	SPD is recruiting additional supervisors to help oversee staff schedule and attendance, and review timesheets for accuracy and compliance.
B.4	SPD is in the process of formalizing staff communication on overtime requirements, to ensure all employees are aware of it and allowed the opportunity to formally respond to accept a preauthorized overtime offer.
B.5	SPD management will regularly obtain and review timekeeping reports for late attendance to identify, implement and document required management actions for addressing non-compliance, and update personnel records as appropriate.
B.6	SPD management will implement a formal process to communicate and document preauthorization of overtime. In addition, SPD should regularly reconcile overtime hours reported to ensure overtime reported is preauthorized, approved and adequately supported, and that any issues are addressed timely.
B.7	SPD management will periodically review timesheets to ensure supervisor approval is obtained and that work hours reported were consistent with the staffing schedule.
B.8	SPD will ensure new processes are implemented across all SPD locations for consistency, and that new attendance logs are continuously maintained and reconciled with hours reported on timesheets.

B. Staff Schedule and Work Attendance – Detailed Discussion

UCSDH Policy (UCSDHP) 670.1 Work Time Attendance provides that “all employees are expected to report to work as scheduled and to work their scheduled hours, shifts, and/or assigned overtime. It is the responsibility of each employee to maintain a satisfactory attendance record.” It also includes the following provisions:

- Individual employee work time availability records are maintained in home departments or unit.
- The department supervisor or leader is assigned responsibility for maintaining work time availability records.
- Managers/Supervisors shall work in consultation with HHR Employee Relations (HHR ER) personnel when initiating progressive discipline documentation.

The policy also establishes guidelines and standards of attendance/availability based on an occurrence threshold over any rolling 12-month performance period. Per the policy, the established acceptable standard is 5 or fewer occurrences within any 12-month period of time. An occurrence may be given for each failure to report to work at scheduled start time, whereby:

- Clocking in after the 7-minute grace period will be one occurrence.
- There is a 7-minute grace period for employees to clock in, however, clocking in during the grace period, three times or more in a calendar month will be one occurrence.

Staffing Schedule and Attendance Records

SPD maintains an attendance book which is updated weekly by floor leads and maintained in a desk binder for each location. The attendance book records SPD employees (permanent and temporary) who call out or report late, including a reason and applicable work shift. This information serves as a reference when reviewing timesheets, and updating staff schedules as shifts can change any time or any day. However, this was not always done due to competing priorities, and leadership staffing shortage.

At HC, when the supervisor retired in February 2022, the Manager was assigned to take on a supervisor role, while overseeing operations, managing projects, and providing staff training. The staffing schedule was updated beginning March through June 2022. The Director also assists in overseeing and managing sterile processing operations while managing other projects and another Perioperative Support Services unit.

Temporary Employee Attendance Records

To evaluate SPD controls for managing staff schedules and work attendance, we reviewed a sample of attendance records approved by the SPD Manager and Director for temporary employees, which include Travelers⁶. Aya Healthcare invoices only when timesheets are approved by a unit supervisor or manager. At SPD, Travelers enter their time through an Aya timekeeping system. The Manager or Director logs in and approves Traveler attendance, usually after a two-week shift, and ensures that Travelers are paid. In reviewing Aya Healthcare data, we noted that the hours entered into the vendor timekeeping system and included in the invoice were at the exact hours of the expected work shift, including lunch breaks of 30 minutes. We verified the work shift with the staffing schedule and were unable to verify four (4) of the 14 (or 26%) sample selected because the staff schedule was not available for the period reviewed. We requested relevant documents / information recorded in the attendance book for verification. However,

⁶ SPD hires temporary employment services through an existing UC-wide contract with Aya Healthcare. Aya Healthcare sends invoices to Accounts Payable for payment processing, for hours reported by temporary employees assigned to each financial unit.

SPD was unable to provide this information and confirmed that the attendance book had not been consistently updated, and that supervisors and floor leads at JMC have not been monitoring Traveler time or reporting issues to the Manager who approves timesheets. We also noted that the scheduled work shift and timesheet data appears consistent and identical. There are also no records of Traveler attendance to verify actual hours worked when approving timesheets. The Director of SPD indicated that SPD management is considering implementation of an attendance log book for all Travelers at the JMC location to closely monitor staff attendance. When implemented, SPD management should ensure records are continuously maintained and reconciled with hours reported on timesheets. SPD should also implement any new process across all SPD locations for consistency.

Occurrences of Failure to Report On Time

We also reviewed a judgmental sample of seven permanent employee timesheets to evaluate compliance with the management of occurrences of failure to report on time using Ecotime late occurrences data from July through March 2022. UCSDH employees enter their time in Ecotime, and supervisors log in to approve attendance and overtime hours entered. We also requested employee records and attendance books to verify whether SPD records were updated for occurrences, and whether occurrences of failure to report on time were addressed in a timely manner. SPD was unable to provide documents for two of the seven sample employees selected. SPD leadership indicated that when the supervisor in the HC location retired, attendance records in the HC location had not continued to be updated, and that these types of occurrences had not been monitored. At JMC, one of the leads had been on leave for a month. SPD leadership had not been able to complete all management tasks due to competing priorities. Per the Director, SPD have documented progressive discipline in employee records for five of employees in coordination with HHR, and that the KOP supervisor will complete documentation of progressive discipline initiation by end of June for the remainder. SPD management should implement a process to identify, implement and document required management actions for addressing non-compliance, and update personnel records as appropriate based on the collection and review of timekeeping reports for late attendance.

Overtime Authorization

Per *UCSDHP 786.1 General Timekeeping*, non-exempt personnel are to clock in and clock out for work hours as they actually work, avoiding incremental overtime. In addition, overtime must be pre-approved by the Department Manager/Leader, when possible. We reviewed overtime records for a judgmental sample of ten employees for selected pay periods between October 2021 and March 2022. We examined payroll report and hours reported in Ecotime, and noted that of the ten selected employees, five could not be verified whether shift hours entered were consistent with the staff schedule. Of the remaining five, only two reported hours in Ecotime consistent with the work shift on the staff schedule. We also noted that three out of the ten selected employees did not have timesheet approval. In addition, we also requested documentation of overtime authorization, SPD confirmed one of the ten employees reported overtime that was not authorized.

The SPD Director usually notifies staff via email when overtime work is required to maintain shift coverage. The Director also explained that lead and supervisor overtime to cover a staffing shortage does not require prior approval as they are expected to ensure shift coverage. In some cases, leads may stay longer and work overtime to finish management reports, or work on new projects, such as training for the new instrument tracking system.

Besides email notification of available overtime work, and timesheet approval, there appears to be no formal process for managing and approving staff overtime, and the reconciliation of attendance logs with timesheets and the staff schedule is not performed to ensure all overtime and attendance reported are accurate. In some cases, timesheets are not reviewed or approved by supervisors or a manager which increases the risk of employees reporting unauthorized overtime. The Director of SPD indicated that SPD is working with HHR and will be establishing a formal process for making available overtime known to all employees. However, this may not address the issue on overtime pre-authorization and reconciliation, so SPD should regularly reconcile overtime hours reported to ensure overtime reported is preauthorized, approved and adequately supported, and that any issues are addressed timely. Also, SPD should establish a process for reviewing and reconciling attendance records to ensure all overtime reported and paid are authorized and accurate.

C.	Equipment Management
SPD equipment records were not regularly reviewed and reconciled to verify all equipment listed is accounted for, and records are accurate and complete. In addition, coordination and communication with Clinical Technology and Equipment Planning appears to be ineffective in ensuring operational requirements are met, and that all equipment is functioning effectively.	
Risk Statement/Effect	
Lack of effective coordination and communication with Clinical Technology and Equipment Planning departments in managing equipment results in inaccurate records, and increases risk of operational failure.	
Management Action Plans	
C.1	SPD will coordinate with Equipment Planning and Procurement to evaluate options that may be available for the unused VPRO sterilizer and other equipment for SPD use, regardless of the financial unit or project to which the cost is charged.
C.2	SPD management will periodically review Campus Asset Management System (CAMS) and Clinical Technology inventory records to verify all equipment listed is accounted for, and ensure records are complete and accurate. Discrepancies listed in Attachment A should be resolved.
C.3	SPD management will regularly review and reconcile equipment depreciation schedules with CAMS and Clinical Technology equipment inventory records to ensure the accuracy of depreciation costs charged to SPD financial units, and evaluate the need for replacement based on the frequency and cost of repairs and maintenance required on fully depreciated equipment.

C. Equipment Management – Detailed Discussion
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Per *University Policy BFB-BUS-29: Management and Control of University Equipment*, the head of the custodial department is responsible for maintaining accurate records for reference, reconciliation and verification of equipment records maintained by Equipment Administrator to ensure records are accurate and complete. *UCSDHP 818.2 Medical Equipment Management Program* also provides that medical equipment management inspections, maintenance, testing, and repair must be effectively coordinated to meet the needs of UCSDH in routine and emergency circumstances. Clinical Technology maintains a

written inventory of all medical equipment, and the user department should promptly report equipment failures, hazards, potential hazards, and operating problems to Clinical Technology immediately.

SPD equipment inventory is maintained by Clinical Technology and Equipment Planning maintains CAMS. SPD does not have a list of equipment leased or owned and have not received or reviewed reports from Clinical Technology and CAMS. SPD monitors equipment efficacy by testing pass/fail rate on a daily basis. In addition, SPD maintains a log of equipment down and reports these issues to Clinical Technology by submitting a work order, and updating the log when equipment is repaired. Clinical Technology also update their records indicating when equipment was last repaired. SPD financial units are not charged for the cost of repairs and maintenance performed by Clinical Technology. In some cases, equipment may be frequently out of service, and Clinical Technology coordinates with the vendor for major repair needs that are required. The cost of repairs performed by external vendors are charged to SPD financial units.

We reviewed Clinical Technology and CAMS records and tested a judgmentally selected sample of equipment listed. In reviewing a sample of equipment purchased and leased for SPD, we noted these records were not complete or accurate. These records help SPD identify operational needs and requirements, and inaccurate records could delay meeting SPD needs and increase operational risks in OR departments supported by SPD. We also reviewed repairs and maintenance expenses charged to SPD financial units and identified blanket Purchase Orders (POs) for the maintenance of sterilizer chambers. No other repairs costs were identified during the period reviewed.

Unused Equipment

During interviews and site visits, we were informed that a VPRO sterilizer equipment was also leased, stored and continues to be paid for, but has not been used. While reviewing equipment test results, SPD leadership was considering a trade-in of an old sterilizer at KOP SPD. Upon consultation with Equipment Planning, however, SPD was informed this would not possible as the equipment was part of a larger lease agreement for KOP.

We consulted with the Procurement Department and Equipment Planning on the VPRO sterilizer that remained unused and in storage for the life of the lease. Procurement verified that two VPRO sterilizers are included under an operating lease agreement charged to a KOP project / cost center. The lease contract was implemented in December 2017 with GE Healthcare on a MES funding mechanism, whereby a variety and portions of equipment are leased on an "equipment schedule". The lease agreement was implemented under a purchase order (PO) (which superseded two other POs), and is expected to mature in June 2023⁷. The VPRO sterilizers had been in storage since the lease began due to installation issues. The equipment was not returned/exchanged within a reasonable timeframe (i.e., normally within the first year of the lease), therefore, it could no longer be traded for different comparable equipment to meet KOP SPD needs. The cost attributable to the unused VPRO sterilizers could not be determined based on the lease terms. However, it appears there is opportunity to create a buyout for an idle asset that could benefit SPD. SPD should coordinate with Equipment Planning and Procurement to evaluate options that may be available for SPD considering the status of the PO. SPD should also ensure timely coordination and communication with Equipment Planning and Procurement related to equipment for SPD use, regardless of the financial unit or project to which the cost is charged.

Equipment Records

⁷ According to Procurement, the lease was extended for a period of six months during the pandemic.

In reviewing sample equipment purchased and leased for SPD, we noted these records were not complete or accurate. One of the equipment listed in CAMS belonged to another department and was erroneously recorded under an SPD unit. We also performed data analytics of equipment records listed in related Clinical Technology inventory, CAMS and depreciation schedules to verify that equipment listed in CAMS and depreciation schedules were consistent, and that both records were also consistent with Clinical Technology records. However, our analysis indicated eight pieces of equipment in CAMS that were not found in the Clinical Technology inventory for HC, and 13 for JMC. Additional verification indicated that for JMC, of the 13 unmatched records, two duplicate serial numbers were also used for different equipment items. **Attachment A** provides a list of capital equipment listed in CAMS that were not included in Clinical Technology inventory records.

Equipment records help SPD identify operational needs and requirements. Inaccurate records could delay meeting SPD needs and increase operational risks in OR departments supported by SPD. SPD should periodically review CAMS information and coordinate with Equipment Planning to ensure records are accurate and complete.

Repairs and Maintenance

Equipment maintenance and repairs are performed by Clinical Technology, and SPD financial units are not charged for repairs and maintenance costs performed in-house by that department. SPD also logs all equipment down and repair needs and coordinates with Clinical Technology for resolution. Repairs and maintenance performed by an external vendor are charged to SPD. In reviewing related charges, we noted that SPD contracted with a vendor for sterilizer chamber cleaning and maintenance, and that vendor charges were either recorded as Repairs and Maintenance or Purchased Services. We also noted invoices and maintenance agreements for two blanket POs include a total of seven pieces of equipment (collectively costing approximately \$1,639 per month) that do not appear to belong to SPD, or that the equipment maintained could not be verified in Clinical Technology inventory.

SPD performs daily equipment tests, and the results would indicate an average pass rate of 50%. At HC, a low temperature sterilizer (STERAD) is problematic due to high sensitivity to failure, therefore the machine repeats cycles and wastes time and chemicals. SPD also maintains a log of all equipment down, and submits a work order to Clinical Technology for repair or coordination of repair with the vendor. We noted that these repairs were not consistently recorded in the Clinical Technology inventory list. During interviews with SPD leadership, we noted that inspections and repairs performed were not always verified with SPD staff. It appears that SPD relies heavily on Clinical Technology to communicate with SPD, and that SPD does not receive or review inventory lists or any Clinical Technology reports on SPD equipment. The lack of coordination and effective communication with offices that maintain equipment could result in operational inefficiencies. SPD should periodically review Clinical Technology equipment inventory to ensure all equipment listed exists and records are complete and accurate. SPD should also reconcile purchase orders and depreciation schedules with CAMS and Clinical Technology inventory, as well as work orders and equipment down logs with Clinical Technology reports, and evaluate the need for replacement or appropriate repairs for fully depreciated equipment.

D.	Space Utilization
SPD space was not utilized efficiently, with continued storage of loaned instruments that remained unused for prolonged periods of time.	

Risk Statement/Effect	
Inefficient use of space contributes to inadequate resources including staff time required to reorganize and reprocess.	
Management Action Plans	
D.1	SPD management will coordinate with UCSDH leadership and vendors to evaluate appropriate action and/or space requirements for storage of unused loaner instruments and/or instrument trays.
D.2	SPD management, in coordination with Perioperative Services leadership, will identify a reasonable timeframe to store vendor-owned instruments in accordance with applicable policy, and, based on that determination, formalize a policy specifically governing the management and timely return of vendor loaner instruments and instrument trays.

D. Space Utilization – Detailed Discussion

SPD units organize and manage storage of instruments processed in several stages to avoid contamination, until ready for use and/or delivery to OR and ancillary departments and clinics. Storage space for SPD supplies is limited and, in some locations, shared with Materials Management. In many cases, vendor instruments are loaned and consigned to OR units, and are processed by SPD. In some cases, loaned instruments remain in SPD storage for an extended period of time, until requested by OR. Instruments on consignment, and other loaned instruments are usually stored separately from UCSDH owned instruments.

During our site visits on May 3rd and May 5th, we noted several loaned instrument trays that are kept and maintained in SPD storage spaces, some of which dated back to 2019, and SPD management mentioned there were also other instrument trays significantly pre-dating 2019. SPD management had expressed concerns for a lack of storage space and cooperation from vendors to address this issue, plus an ongoing financial cost while on loan. SPD management also indicated that in some cases, vendors bring instrument trays that remain unused. When asked for a list of their trays on consignment, the vendors were unable to provide one. SPD management was unaware of any contracts or agreements related to loaned instruments. Vendor-owned instruments are usually loaned to ORs to meet instrumentation requirements. However, it appears there is no specific guidance for how long loaned instruments should remain in the facility. SPD management should coordinate with UCSDH leadership and vendors to evaluate appropriate action and/or space requirements for the storage of unused loaner instruments and/or instrument trays.

Also, SPD management should evaluate and identify a reasonable timeframe to store vendor-owned instruments in accordance with applicable policy. Based on that determination, SPD management should formalize a policy governing vendor loaner instruments and instrument trays to best ensure their proper management and return to vendors in a timely basis.

We have included photos of specific older instruments trays noted with reference to the procedure date, which are all from the same vendor, as well as photos of the general area in which these loaner instrument trays are taking up significant storage space in the JMC SPD in **Attachment B**.

**ATTACHMENT A
LIST OF CAPITAL EQUIPMENT IN CAMS NOT INCLUDED IN CLINICAL TECHNOLOGY INVENTORY RECORDS**

UCID	DESCRIPTION	MODEL NUMBER	SERIAL NUMBER	PO REFERENCE NUMBER	BUILDING	ROOM	CURRENT VALUE
056020022	CARTS, STERILIZER/DECONTAMINATION	ATLAS	0105505-21	500014	6974 - HC MED CENTER	STERPROC	\$ 12,422
056020023	CARTS, STERILIZER/DECONTAMINATION	ATLAS	0106605-13	500014	6974 - HC MED CENTER	STERPROC	\$ 12,422
056020024	CARTS, STERILIZER/DECONTAMINATION	ATLAS	0106605-11	500014	6974 - HC MED CENTER	STERPROC	\$ 12,422
056020348	STERILIZERS, STEAM, DRY, GAS,	FH03082	NA	5600101	6974 - HC MED CENTER	OR	\$ 170,390
066020152	STERILIZERS, STEAM, DRY, GAS,	AMSCO CENTURY	UNKNOWN	55600009	6974 - HC MED CENTER	OR	\$ 55,443
086020176	STERILIZER, STEAM, DRY, GAS, AUTOCLAVE	00-10033-2-001	10033080298	CA9001	6974 - HC MED CENTER	2-310	\$ 47,657
106020222	STERAD 100 NX	100NX	1041100321	CA5205	6974 - HC MED CENTER	2ND FL CENTRAL SERV	\$ 188,790
166020145	TEMPERATURE BOOSTER	A1017	UNKNOWN	559752	6974 - HC MED CENTER	2-303	\$ 20,748
166027590	WORKSTATION	CG55	0813ST013-0060*	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 10,220
166027591	WORKSTATION	CG55	0414ST013-0059*	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 10,220
166027592	WORKSTATION	CG55	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 10,220
166027593	WORKSTATION	CG55	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 10,220
166027594	WORKSTATION	CG55	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 10,220
166027595	WORKSTATION	CG55	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 10,220
166027596	CONVEYER SYSTEM	SCS2W	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 12,983
166027597	CONVEYER SYSTEM	SCS2W	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 12,983
166027600	SINK	CCPS3112035	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 21,209
166027601	SINK	CCPS3112035	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 21,209
166027608	STERILIZER	SCS2W	3617814004	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 12,983
166027609	SINK	CCPS3112035	NONE	JMC1038	7063 - JMC BED TOWER	JMC-LL-640	\$ 21,209
166027633	COMPACTOR	TA7000/SS	NONE	JMC1075	7063 - JMC BED TOWER	JMC-LL-633	\$ 10,795

*Duplicate serial number existed for different asset (Ultrasonic Cleaner Model CRP217RL) in Clinical Technology Inventory

ATTACHMENT B – LOANER INSTRUMENT TRAY STORAGE



Figure 1 - VENDOR LOANERS NOVEMBER 11, 2019 AND FEBRUARY 12, 2021



Figure 2 - VENDOR LOANERS MARCH 15, 2021 AND JANUARY 12, 2022

ATTACHMENT B (CONTINUED) - OVERALL STORAGE AREAS WITH LOANER INSTRUMENT TRAYS

