UNIVERSITY OF CALIFORNIA, DAVIS
AUDIT AND MANAGEMENT ADVISORY SERVICES

UC Davis Health
Clinical Engineering
Audit & Management Advisory Services Project #22-11

June 2022

Fieldwork Performed by:
Sarah Flower, Senior IT Auditor
Janet Cox, Principal Auditor

Reviewed by:
Ryan Dickson, Associate Director

Approved by:
Leslyn Kraus, Director

AMAS Project #22-11

MANAGEMENT SUMMARY

Background

As part of the fiscal year (FY) 2022 audit plan, AMAS performed an audit of Clinical Engineering. Clinical Engineering manages all aspects of clinical technologies including direct clinician support, FDA issues, and equipment maintenance. Clinical Engineering provides various services to departments within UC Davis Health (including the primary care network clinics, and Shriners Hospital for Children, Northern California) such as pre-purchase product evaluations, medical equipment planning, device installation, and repair and maintenance services. Equipment managed by Clinical Engineering is recorded in their computerized maintenance management system.

The computerized maintenance management system (CMMS) currently in place at Clinical Engineering is called AIMS. AIMS has been in use at Clinical Engineering for over 13 years. It is a web-based software system that houses maintenance records for devices managed by Clinical Engineering. The system stores equipment records, work orders, and maintenance scheduling. Clinical Engineering is in the process of submitting a request for proposal for acquiring a new CMMS.

Equipment that has been inspected by Clinical Engineering is marked with a sticker denoting the last date of maintenance.

Purpose and Scope

The purpose of this audit was to assess controls and processes for management of medical devices by Clinical Engineering. In order to accomplish these objectives, we reviewed medical device data in the AIMS database; evaluated reports generated by Clinical Engineering staff; interviewed relevant management and staff; reviewed applicable federal policies and guidance; and performed an on-site audit on a sample of medical devices. Our on-site review included seven UC Davis Health departments across multiple locations.

The timeframe under review was January 2021 through December 2021.

Conclusion

We found that Clinical Engineering has struggled with staffing shortages, and that this has impacted its ability to perform required maintenance. Leadership in Clinical Engineering recognized this and contracted with an external firm for a four-month period in calendar year 2021 to help them address past due maintenance, which resulted in a 44% reduction in equipment flagged as non-compliant.

We also concluded that:

- equipment maintained by Clinical Engineering was improperly tagged, untagged, or non-compliant with required maintenance schedules;
- there are data quality issues within the CMMS; there may be inappropriate levels of access within the CMMS at Clinical Engineering;

- current methods for departments to report maintenance concerns to Clinical Engineering may result in communication breakdowns; and
- there is no procedural documentation for Clinical Engineering processes or departmental policies.

Observations, Recommendations, and Management Corrective Actions

A. Communications and Inventory Processes

An inspection performed during audit fieldwork found equipment not properly tagged, untagged, or non-compliant with required maintenance schedules.

When Clinical Engineering performs maintenance on a piece of medical equipment, the technician applies a sticker to the equipment to signify when it has been inspected, and when the next inspection is required. As part of our review, we visited seven departments[1] to test planned maintenance compliance and the inspection history documented in AIMS. We also inspected medical devices at each of these locations to document the information reflected on the inspection stickers, if any.

Of 230 pieces of equipment observed, we found 26 devices (11%) with past due maintenance stickers; 62 devices (27%) with no maintenance sticker; 11 devices (5%) with no asset sticker;[2] and 131 (57%) were current in the planned maintenance.

The 11% of equipment found to be past due for planned maintenance is consistent with non-compliance estimations provided by Clinical Engineering. However, equipment without inspection stickers are not included in those estimations, so based on a sample of 230, we estimate an actual noncompliance rate closer to 43%[3].

The volume of equipment found not to possess a Clinical Engineering inspection sticker supports a conclusion that there is a lack of coordination between Clinical Engineering and the Purchasing department.[4] Discussion with the two groups confirmed confusion over which items should be routed to Clinical Engineering for initial inspection and entry into the CMMS.

Additionally, the units included in the site visit conducted by AMAS confirmed that they do not receive reporting from Clinical Engineering to alert them to potential maintenance concerns, such as maintenance that is past due or equipment that could not be located.

Finally, the CMMS includes numerous items for which Clinical Engineering may no longer be responsible. This could be because the equipment is no longer in use, does not require

[1] Two departments at UCDH Midtown location, three within the ACC, two in the main hospital and the same day surgery center.
[2] These 11 devices also had other various issues, including maintenance stickers with no noted frequency, no maintenance sticker, or expired maintenance stickers.
[3] 43% represents the overall non-compliance rate; 38% were included in Clinical Engineering's inventory system while the other 5% did not have asset stickers and were not in the inventory system.
[4] When placing an order, Purchasing must indicate if the equipment should be delivered to Clinical Engineering for initial inspection.

planned maintenance, or maintenance was reassigned to Plant Operations and Maintenance (PO&M). This includes equipment such as refrigerators, microwaves or other non-medical devices. Documenting types of equipment to be inspected by Clinical Engineering vs PO&M can provide clarity to Purchasing, the acquiring department, and result in more accurate information in the CMMS. Having improperly tagged equipment or equipment that is not following required maintenance schedules may lead to non-compliance with Joint Commission[5] standards.

Recommendations

Clinical Engineering should perform a full inventory in order to ensure all items under the department's purview are captured in the CMMS, and are being regularly inspected.

Further, there is a need for improved communications between Clinical Engineering and the units it serves, as well as with purchasing staff.

Finally, to assist in identifying any ongoing issues, Clinical Engineering should develop a process for non-technical staff to conduct random audits of equipment throughout UCDH for initial inspection and planned maintenance compliance.

Management Corrective Actions

1) By December 15, 2022, Clinical Engineering will perform a full inventory reconciliation.

   Owner: Clinical Engineering

2) By August 31, 2022, Clinical Engineering will develop and disseminate guidance for departmental staff for how to communicate expired maintenance stickers, maintenance requests, untagged equipment, and noting that a piece of equipment should be routed to Clinical Engineering for initial inspection on purchasing requests.

   Owner: Clinical Engineering

3) By August 31, 2022, Clinical Engineering will develop guidance to assist purchasing staff in determining which medical devices should be routed through Clinical Engineering for initial inspection.

   Owner: Clinical Engineering

4) By October 31, 2022, Clinical Engineering will develop a process for regularly reporting pertinent information (such as departmental device inventories, upcoming scheduled maintenance, and missing/end-of-life device lists) to the departments it provides services to.

   Owner: Clinical Engineering

[5] The Joint Commission is a United States-based organization that provides accreditation to health care organizations and programs.

5) By October 31, 2022, Clinical Engineering will develop a process for quarterly audits of planned maintenance compliance at various locations.

   Owner: Clinical Engineering

B. Computerized Maintenance Management System (CMMS) Data Quality

Our review revealed issues with data quality and integrity within Clinical Engineering's CMMS.

Clinical Engineering's CMMS contains records of medical equipment owned or leased by UC Davis Health. During our review of data pulled from the system, we noted several issues with the data contained therein.

Certain search functions are not usable because fields are used inconsistently, or are left entirely blank. For example, many medical devices that are connected to the network do not contain network information, and therefore do not appear in searches specifying for "networked medical devices." There were also devices with a listed criticality level of "00," which is not on Clinical Engineering's scale of 1-4.

Data quality issues have arisen due to the age of the system and varying direction from management and administrative guidance as to what should be included in the CMMS.

A lack of data integrity may lead to incomplete or unreliable inventory records, which we observed in MCA (A). It also impedes the department's ability to accurately understand what inventory is currently under their purview.

Recommendations

Clinical Engineering should address data inconsistencies in the CMMS before migrating to a new system. This includes removing devices that are not managed by Clinical Engineering, removing codes (such as location codes) and fields that are no longer being used, ensuring that there are no devices with incorrect criticality levels, and removing items that are no longer in use as identified during inventory reconciliation.

Management Corrective Action

1) By December 15, 2022, Clinical Engineering will perform data cleaning procedures over its CMMS.

   Owner: Clinical Engineering

C. Access Management

There may be inappropriate levels of access within the CMMS at Clinical Engineering.

The CMMS for Clinical Engineering can only be accessed while a user is on-site at the UC Davis Medical Center or connected through a UCDH VPN. However, appropriate levels of access and regular user access reviews should still be maintained. According to UC Policy BFB-IS-3, "when granting access to Institutional Information classified at Protection Level 3

or higher, Units must: Segregate access rights management so that requestors, approvers and grantors are unique roles assigned to separate individuals, or implement compensating controls to address risk associated with the combination of duties, and maintain records that document changes to access rights and the related approvals… Units must limit access to authorized users and prevent unauthorized access to Institutional Information and IT Resources."

We found that users with administrator-level privileges have the ability to delete audit logs from the system. We also found users who had not logged into the system for more than five years, and users with elevated privileges who are not a part of the Clinical Engineering department.

Clinical Engineering does not maintain documentation of user access profiles, and does not regularly perform user access reviews. Unauthorized or inappropriate access may lead to unintended changes to the CMMS.

Recommendation

Clinical Engineering should document user access profiles and determine appropriate assignment of roles according to job duties. Clinical Engineering should also regularly perform user access reviews over its system.

Management Corrective Actions

1) By October 31, 2022, Clinical Engineering will document user access profiles and permissions, and confirm duties have been separated appropriately through discussions with the UCDH Information Security Office.

   Owner: Clinical Engineering

2) By September 30, 2022, Clinical Engineering will perform a user access review for AIMS.

   Owner: Clinical Engineering

3) By September 30, 2022, Clinical Engineering will document and implement a process for regularly reviewing user access for its CMMS.

   Owner: Clinical Engineering

D. Work Order Communication Methods

Current methods of contacting Clinical Engineering may result in communication breakdowns.

We surveyed a sample of departmental staff, who indicated that there is confusion over how to contact Clinical Engineering in the case of a maintenance request. Currently, Clinical Engineering fields all maintenance requests via telephone only. Per COBIT 5,[6] service

[6] Control Objectives for Information and Related Technologies (COBIT) is a framework for information technology management and governance.

desks should "log all service requests and incidents, recording all relevant information so that they can be handled effectively and a full historical record can be maintained."

Clinical Engineering does not have a service-desk email address specifically for customers to submit their requests. Further, Clinical Engineering does not utilize a help desk ticketing system. As a result, work orders may be lost, and there is no mechanism for reporting on customer service metrics.

Recommendation

Clinical Engineering should implement an electronic system of contact specifically for customer work order requests.

Management Corrective Action

1) By July 31, 2022, Clinical Engineering will create an electronic system for customers to initiate contact for requests and other inquiries.

   Owner: Clinical Engineering

E. Departmental Documentation

There is no procedural documentation for Clinical Engineering processes, and no departmental policies.

A key individual within the department who oversees the majority of data entry for the CMMS is retiring in 2022. Currently, there is no procedural documentation for entering data into the current CMMS, or other processes such as performing inspections, maintenance requests, or identifying and handling end-of-life equipment.

Clinical Engineering is planning to retain this procedural knowledge by hiring and training a replacement, but Clinical Engineering should also maintain written documentation of these processes. Clinical Engineering also does not maintain any departmental policies. A lack of policies and procedures can lead to inconsistent practices and a loss of institutional knowledge.

Recommendation

Clinical Engineering should develop procedural documentation detailing data entry, inspection, maintenance, end-of-life device management, and reporting processes at Clinical Engineering.

Management Corrective Action

1) By August 31, 2022, Clinical Engineering will develop and properly publish relevant procedural documentation and departmental policies.

   Owner: Clinical Engineering

***