UCIRVINE | INTERNAL AUDIT SERVICES

Biomedical Engineering

Internal Audit Report No. I2019-204

August 16, 2019

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INTERNAL AUDIT SERVICES
IRVINE, CALIFORNIA 92697-3625

August 16, 2019

**CHARLES ADAMS
DIRECTOR
BIOMEDICAL ENGINEERING**

**RE: Biomedical Engineering Audit
Report No. I2019-204**

Internal Audit Services has completed the limited review of medical equipment inventory and maintenance under Biomedical Engineering. IAS has attached the final report.

We extend our gratitude and appreciation to all personnel with whom we had contact while conducting our review. If you have any questions or require additional assistance, please do not hesitate to contact me.

Mike Bathke
Director
Internal Audit Services

Attachment

C: Audit Committee
    Chad Lefteris – Chief Operating Officer, UCI Health

I.   MANAGEMENT SUMMARY

In accordance with the fiscal year (FY) 2018-2019 audit plan, Internal Audit Services (IAS) conducted a limited review of the Biomedical Engineering (BE) department regarding medical equipment inventory and maintenance. In general, department controls and processes appear to be functioning as intended. Based on the audit work performed, some internal controls need improvement and BE should strengthen them to minimize risks, ensure compliance with University policies and procedures, and/or support best business practices. Specifically, the following concerns were noted.

Preventative Maintenance (PM) Timeliness – IAS found one high-risk piece of equipment, a circulatory assist unit, overdue for PM inspection. The inspection was scheduled for May 2019, but as of August 8, 2019, the inspection had not been done and is now two months overdue. In addition, IAS noted at least seven bedside monitors overdue for PM inspections. BE scheduled the monitors for PM inspections on April 2019, but as of June 20, 2019, the inspections had not been completed. These observation details are discussed in section V.1

Database Accuracy– BE did not always update the medical equipment database, *Asset Plus*, to reflect equipment status changes. Fourteen pieces of equipment were determined to be no longer in use or inactive, and were not recorded as such in the database. In addition, one new oscilloscope initially inspected and assigned to an annual PM plan with the proper PM tags placed upon it did not have its next PM date entered into the database. Without this date, the required annual inspection would not appear on the PM schedule and the inspection could lapse. These observation details are discussed in V.2.a.

Access Management – Two individuals who no longer needed access continued to have access to *Asset Plus*. In addition, IAS noted another individual with full privilege access to *Asset Plus* was not utilizing this account. This is discussed in section V.2.b.

Preventative Maintenance (PM) Tags – Future inspection dates documented on the PM tags affixed to the equipment did not always agree to the information in the database. Additionally, three high-risk pieces of equipment with outdated tags appeared as if PM inspections were overdue; instead, the equipment did not have the correctly dated tags in place. This is discussed in V.3.

Physical Security of Equipment – Equipment in the custody of BE is not physically protected from loss and theft at all times. BE shares office space with other departments so non-BE employees have access to high dollar medical and testing equipment. No controls are in place to safeguard this equipment. This is discussed in section V.4.

Department Website – BE does not have a department website to provide visibility and access to information for equipment users. This is discussed in V.5.

II. BACKGROUND

The primary mission of BE is to provide biomedical engineering services for approximately 18,000 pieces of equipment for the University of California, Irvine (UCI) Medical Center and clinics within the School of Medicine. BE provides most of these services to optimize healthcare delivery through medical technology while ensuring that medical equipment used in clinical settings is effective and safe to use with patients, employees, and other individuals. As of 2014, BE services are no longer outsourced to Philips Medical Systems. UCI employees now perform most biomedical engineering operations.

When fully staffed, the BE department consists of twelve staff members that include a Director, nine technicians, and two administrative employees.

III. PURPOSE, SCOPE AND OBJECTIVES

The primary purpose of the audit was to perform a general review of BE to assess business risk, internal controls, and compliance with University policies and procedures. The scope focused on certain operational and financial activities for FY 2018-2019.

The audit included the following objectives.

1. Verify that BE performed PM inspections on new medical equipment before the equipment was placed in service. Also, verify that BE documented the equipment inspections in the database and attached the proper tags.

2. Verify that BE performed timely PM inspections on existing medical equipment placed in service. Verify BE documented inspections in the database and attached tags to each piece of medical equipment.

3. Determine whether high risk equipment not assigned to a PM had documented justifications. In addition, determine whether BE made a genuine effort to locate missing medical equipment before removing them from the PM plan.

4. Assess that the equipment in the custody of BE was physically secured to prevent loss and/or inappropriate use.

5. Evaluate the access controls to the equipment database to verify that it is limited to authorized individuals and privileges are set at the appropriate levels.

IV.   CONCLUSION

In general, departmental controls and processes appear to be functioning as intended. However, business risks and internal controls and processes could be enhanced in the areas of timely PM inspections, updating the equipment database, *Asset Plus* access management, accuracy of the PM tags to ensure agreement with the equipment database, physical security of equipment, and having a department website.

Observation details and recommendations were discussed with management, who formulated action plans to address the issues. IAS presents these details below.

V.   OBSERVATIONS AND MANAGEMENT ACTION PLANS

1. Preventative Maintenance (PM) Timeliness

Background

BE uses a risk ranking system to evaluate all medical equipment at the time of entry into the database. The risk ranking is comprised of a score based on equipment functions, failure risk (potential harm to patient or staff with failure), maintenance requirements, and equipment history. BE identifies equipment falling into the highest tier as high-risk.

IAS selected a sample of high-risk medical equipment from the database for review to ensure timely PM inspections in accordance to the PM plan assignment, proper tagging of equipment, and correct information input into the equipment database. IAS reviewed equipment at various locations including the Medical Center, Gottschalk Medical Plaza, Gavin Herbert Eye Institute (GHEI), and the Sleep Clinic. While conducting fieldwork, IAS selected an additional sample of non-high-risk equipment for review.

Observation

BE may not have completed PM inspections in a timely manner.

- One of the sampled equipment items was a circulatory assist unit assigned to the Surgery-Operating Room department located at the Medical Center. According to the database, this high-risk piece of equipment was due for PM inspection on May 2019, but as of August 8, 2019, BE had not completed the inspection and is two months overdue. Additionally, the PM tags found on the unit were incompatible with the information in the database. The tags note the last PM inspection on January 2019 with the next PM on January 2020.

- IAS also observed that the PM inspections for at least seven bedside monitors were overdue at the Sleep Clinic, an off-site location. The PM tag stickers indicated that April 2019 was the next PM scheduled, but as of June 20, 2019, BE had not completed the inspection. Although not high-risk, the equipment still require periodic PM inspections. The PM tags placed on the

units correctly noted the next PM due date of April 2019, however, the next PM date was mistakenly entered as April 2020 in the equipment database. As a result, the equipment did not appear on the 2019 PM schedule. Upon discovery, BE completed the PM inspection on June 21, 2019, two months after the due date. Management should ensure BE staff accurately enter future PM dates into the database so that they timely perform PM inspections.

Management Action Plan

Management will immediately instruct staff to ensure PM inspection dates are carefully and accurately entered into the equipment database. The PM inspection for the circulatory assist unit is in progress and will be completed by August 30, 2019. Once completed, the proper PM tags will be placed on the unit. Management will also perform periodic audits by running equipment database reports to ensure the dates for PM inspections were entered accurately by October 2019.

2. Asset Plus

a. Database Accuracy

Background

Since 2015, BE has been utilizing the database software *Asset Plus* to manage all medical equipment inventory throughout their lifecycle. The database allows BE to track all maintenance activities, optimize use of assets, and make sound decisions when buying or replacing equipment. BE should record all medical equipment activities in *Asset Plus*.

Observation

Through sample testing, IAS found that the database did not always reflect changes to medical equipment.

- IAS sampled 54 equipment items and 14 (26 percent) items were no longer in use or inactive, were not recorded as such in the database, and thus appeared as active equipment.

- BE initially inspected a new oscilloscope located at the Gottschalk Plaza and assigned it to an annual PM plan on March 6, 2019. BE placed the proper PM tags on the high-risk equipment noting the next PM as March 2020. Review of the database revealed that the next PM date of March 2020 was missing and not entered into the database. Upon audit notification, BE entered the appropriate PM date into the database on July 11, 2019, four months later.

Maintaining an accurate inventory database on an ongoing basis allows for proper oversight of medical equipment management. Inaccuracy of inventory information can be fatal. Consequently, it is crucial that the inventory database is consistently accurate and up-to-date. Furthermore, management should continue to implement a more effective and robust system, preferably utilizing a web-based system, that will provide users ease in accessing the database at any location.

Management Action Plan

By January 2020, management anticipates to implement a new web-based medical equipment management system that will allow users to update the database with more accessibility. In the meantime, management will remind staff to update the database promptly as changes occur to ensure the database's accuracy. In addition, by October 1, 2019, the medical equipment database will be reviewed and any equipment that appear inactive will be removed from the database.

b. **Access Management**

Background

In order for users to access *Asset Plus*, they must also have access to *Citrix*, a software used to securely access applications or even entire desktops. To ensure that *Asset Plus* access and permission levels are authorized and commensurate with job functions, IAS interviewed BE management and analyzed both the *Asset Plus* users list and the *Citrix* users list.

Observation

A review of the *Asset Plus* and *Citrix* users list showed that two individuals who no longer needed access continued to have active *Citrix* and *Asset Plus* user accounts. According to management, when staff members separate from UCI Health, management assumed that their access to *Citrix* would be automatically deactivated. However, this does not happen automatically, and BE management must communicate deactivation of user accounts in *Citrix* to UCI Health's Access Provisioning team.

The roles for the above individuals in *Asset Plus* were set to "Maintenance," which does not provide the ability to add, modify, or delete data, such as preventative maintenance schedules; however, it does give users the ability to input readings from tested equipment as well as to open and close work orders. This poses the risk of unauthorized access, inaccurate information being entered into the system, and the premature closure of work orders, potentially resulting in delays to equipment repairs or having unrepaired equipment being returned to service thus posing a serious risk to patient safety.

In addition, IAS learned that one BE manager had access to *Asset Plus* with an "Administrator" role with full privileges. However, the manager was not utilizing this account and had not accessed *Asset Plus* for some time. The "Administrator" role has the ability to delete; modify; and enter data, including preventative maintenance schedules; add user accounts; and open or close work orders. An unused but active user account creates the risk of unauthorized individuals gaining access through this account and performing unauthorized modifications and deletions of equipment information, including repairs and preventative maintenance information, which can result in serious risks to patient safety.

Lastly, IAS identified 24 user accounts on the *Asset Plus* users list that are not recorded on the *Citrix* users list. These are deactivated *Citrix* accounts, and although they technically cannot access *Asset Plus* without *Citrix* access, they still pose a small risk and as a best business practice, IAS recommends that BE deactivate these accounts in *Asset Plus* as well.

Management Action Plan

Management will delete the manager's account in *Asset Plus*, and will reach out to the UCI Health Access Provisioning Team to remove the two individuals that still have access through *Citrix*. Regarding the 24 user accounts that are on the *Asset Plus* users list, management is looking into options on how to best handle these accounts. These users cannot be deleted from *Asset Plus* without also deleting their previous activity, which must be preserved. Management is looking to see if these accounts can be deactivated without deleting them, but at a minimum, will delete accounts that have not had activity for a long time. Management plans to have a resolution by September 30, 2019.

3. Preventative Maintenance (PM) Tags

Background

PM tags attached to medical equipment indicate the last PM inspection performed and the future PM inspection (month/year). Once a PM inspection is completed, BE places a new tag on the equipment. The dates noted on the PM tags should agree to the dates recorded in the database.

BE technicians did not always complete PM inspections, as some medical equipment require the vendor/manufacturer to perform the inspection. BE technicians are responsible for ensuring vendor/manufacturer inspections are completed by the due date indicated on the PM tags. BE technicians must also obtain the service inspection reports from the vendors/manufacturers before placing the PM tag on the equipment.

Observation

The PM tags attached to medical equipment was inconsistent with the database and testing found the following:

- On June 13, 2019, IAS noted that one high-risk piece of equipment, a $6.5 million radiotherapy system assigned to Radiation Oncology, had a PM tag that indicated that the last PM was January 2019 and the next PM was January 2020. However, according to the equipment database, the last PM was March 2019 and the next PM scheduled was for June 2019. Not only

were the dates inconsistent but so was the frequency of the PM inspections. This equipment requires quarterly inspections and not annual as noted by the PM tags. BE did not update the PM tags when the service report was received from the vendor/manufacturer.

Additionally, as of July 11, 2019, the PM inspection due June 2019 is overdue and is still in progress. According to the database, the BE technician contacted the vendor on June 10, 2019, and is still waiting for a return call. Although a month has passed, BE has not performed any further follow-up.

- IAS also noted that another high-risk piece of equipment, a $232 thousand laser excimer located at the Gavin Herbert Eye Institute (GHEI) clinic, had outdated PM tags that indicated that the next inspection was due March 2019. However, review of the database found that the next PM was actually due March 2020. BE noted in the database that the vendor/manufacturer performed the inspection in February 2019, however, they did not follow-up with the vendor until May 23, 2019, three months later, for the inspection service report. The PM tag had not been placed on the equipment as the BE technician was awaiting the service report from the vendor/manufacturer. On June 20, 2019, BE obtained a copy of the vendor inspection report from the GHEI department. BE did not perform timely follow-up with the vendor to ensure the PM inspection report was received. With the PM service report now on file, the updated PM tag can now be placed on equipment.

  While at the GHEI location, IAS also observed another laser excimer with outdated PM tags. The PM tag indicated that the next inspection was due April 2019, which would appear overdue as of June 20, 2019. However, review of the database found that the April 2019 inspection was completed and the next PM was due July 2019. The database had the vendor service inspection report attached but the current PM tag had not been placed on the equipment.

For PM inspections completed by the vendor, BE technicians should set calendar reminders to ensure timely and consistent follow-up with the vendors to obtain service inspection reports, especially for high-risk equipment. Once BE receives the inspection service reports, the updated PM tags should be immediately placed on the medical equipment.

Management Action Plan

By August 30, 2019, for the equipment mentioned above, management will ensure the proper PM tags are placed on the equipment and are in agreement with the equipment database.   BE management will instruct staff to set calendar reminders for PM inspections performed by the vendor/manufacturer to ensure service inspections reports are followed up on and received timely.

4. Physical Security of Equipment

Background

BE recently moved into new office space in April 2019. BE shares this office space with other Medical Center departments. The BE office stores medical equipment being repaired and other miscellaneous equipment valued at about $200 thousand. Testing equipment valued at about $100 thousand is also stored in the BE office. IAS also noted approximately $22,500 worth of technician tools in the same office space.

Observation

Valuable equipment stored at the BE office is prone to theft as there are no internal or physical controls to safeguard equipment. IAS noted numerous instances when non-BE staff walked in and out of the BE office.

Management should consider adding a partition wall to separate the BE office from the other departments and requiring ID badge entry into their office space.

Management Action Plan

By August 30, 2019, management will contact Police/Security to conduct a physical security assessment of the BE office and consider any proposed corrective actions to be implemented.   The proposed improvements may include:

- Adding a partition wall to separate the BE office from the other departments and limiting access to the medical equipment in BE's custody to only BE employees; and

- Installing an ID badge entry system to access the BE office.

5. <u>Department Website</u>

Observation

BE does not have a department website that will provide more visibility and improve communication with equipment users. The website should include detailed instructions and procedures on how to request corrective maintenance rather than having staff rely on hearsay. BE could also use the website to efficiently manage and track corrective action requests.

Having a website has many advantages and benefits such as improving customer service, making services accessible at all times, and providing access to BE information.

Management Action Plan

By January 1, 2020, BE will create a department website that will include information on services provided, how to request corrective maintenance on equipment, and contact information. Management will also explore the idea of integrating the website into electronically managing medical equipment corrective action requests once the new database is implemented.