

20-203 Biomedical Device Maintenance

EXECUTIVE SUMMARY

We have completed our audit of biomedical device maintenance. This audit was performed at the request of the UTHealth Audit Committee and was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing*.

Background

The maintenance of biomedical devices is critical to reducing costs, providing timely patient treatment, and reducing mortality and other risks associated with patient care. It is an integral part of the life cycle of such devices.

Audit Objectives

Our objective was to determine whether controls around biomedical device maintenance are adequate and functioning as intended. Specifically, we wanted to determine if:

- Biomedical device maintenance policies and procedure are in place.
- Biomedical device maintenance is performed according to established schedules/industry standards.
- Biomedical device maintenance fees are only paid for active and in-service devices.

Scope

UT Physicians and UTHealth biomedical devices as of June 30, 2021.

Conclusion

Overall, controls around biomedical device maintenance are adequate and functioning as intended. We noted the following opportunities for improvement:

#	Audit Observation Summary	Risk	Risk Rating
1	Instances were noted in which biomedical device maintenance was not performed according to established schedules/industry standards.	Increased costs and/or negative impacts to patient care.	High
2	Inventory records are not being updated and some biomedical devices are missing and unaccounted for.	Inaccurate inventory records and/or misappropriation of assets.	High

AUDIT OBSERVATIONS & MANAGEMENT RESPONSES

<p>#1 - Maintenance</p> <p>Cause Biomedical device maintenance is not being performed according to established schedules/industry standards.</p> <p>Risk Increased costs and/or negative impacts to patient care.</p> <p>Condition We noted institutional policies and procedures governing biomedical device maintenance have not been formally established.</p> <p>We selected a sample of 25 active biomedical devices from the IT Asset Management System (ITAMS) - which subsequently migrated to ServiceNow - and conducted a site inspection to verify maintenance is being performed according to the Emergency Care Research Institute's <i>Inspection and Preventive Maintenance Procedures</i> (IPM). We noted one device for which maintenance was not performed according to the IPM.</p> <p>While onsite:</p> <ul style="list-style-type: none">• We selected a random sample of 15 biomedical devices and noted 13 were not under a service contract - or the service contract was not available. We noted the following issues:<ul style="list-style-type: none">- 2 devices with no record of maintenance performed.- 2 devices with past-due maintenance service dates (both over 1 year).• We requested reports detailing maintenance fees paid in order to verify each biomedical device is active and in service. Clinical management was unable to run the requested reports and, as a result, we were unable to perform this procedure. <p>Criteria Healthcare IT management informed us maintenance for biomedical devices follows the IPM.</p>
<p>Recommendation We recommend management:</p> <ul style="list-style-type: none">• Develop and implement institutional policies and procedures governing biomedical device maintenance and ensure maintenance is conducted on devices according to established schedules/industry standards.• Conduct maintenance on the biomedical devices noted as exceptions. <p>Rating High</p> <p>UT System Priority Findings Matrix Mapping (see Appendix A) Effectiveness and Efficiency: Medium probability of a mission critical activity failing with major regulatory, reporting consequences.</p>
<p>Management Response #1 We will develop UT Physicians (UTP) Biomedical Equipment Maintenance policies and procedures that address the specific needs and requirements of biomedical maintenance. These policies and procedures will follow manufacturer recommendations for maintenance of medical equipment. Once</p>

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finalized, the procedures will be distributed to the clinical enterprise and communicated at future UTP Clinic Leadership and DMO meetings.

Responsible Party

Saeed Chaudhry, Vice President, Executive Director Operations - UTP

Katherine Hinze, Director, Clinical Effectiveness and Patient Safety - UTP

Implementation Date

March 11, 2022

Management Response #2

UTP clinic managers will request service maintenance on the noted exceptions.

Responsible Party

Saeed Chaudhry, Vice President, Executive Director Operations - UTP

Implementation Date

March 11, 2022

#2 – Inventory Records

Cause

Inventory records are not being updated and some biomedical devices are missing and unaccounted for.

Risk

Inaccurate inventory records and/or misappropriation of assets.

Condition

We selected a sample of 25 active biomedical devices from ITAMS, performed a site inspection, and noted the following issues:

- 8 of 25 (32%) reflected an incorrect status in ITAMS. Clinical management informed us the devices were surplus, sold, or transferred to different areas.
- 2 of 25 (8%) were not onsite and could not be accounted for by clinical management.

While conducting site inspections, we selected a random sample of 15 biomedical devices and noted one that had an inventory tag but was not reflected in ITAMS. Additionally, during our review of maintenance report records while onsite, we noted two devices listed that could not be located at the clinic.

Criteria

IT SOP-015 *Medical and Scientific Device SOP* requires medical and scientific devices to be appropriately accounted for and inventoried throughout their lifecycle from acquisition to disposition, regardless if devices are procured or received via a donation or other methods, and regardless of asset value or cost.

Recommendation

We recommend management:

- Update the inventory system for the biomedical devices noted as exceptions and conduct research to resolve those that could not be accounted for by clinical management.
- Develop and implement a process to ensure biomedical devices are accurately reflected in the inventory system.

Rating

High

UT System Priority Findings Matrix Mapping (see Appendix A)

Capital Impact: Medium potential for significant financial loss of use of assets with reputational side effects.

Management Response #1

For the noted exceptions, UTP Clinical management, the Biomed group, and Capital Assets will update the inventory system, as well as conduct research to resolve those that could not be accounted for by clinical management.

Responsible Party

Gene Chandler, Director of Integration, McGovern Medical School
Heidemarie Hellriegel, Assistant Director of Capital Assets Management

Implementation Date

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Management Response #2

The Biomed group will track new purchases and work with clinical management to update ServiceNow once biomedical devices arrive onsite. Additionally, a new distribution group - including Clinical Operations, Capital Assets, and the Biomed group - will be created for interdepartmental transfers, departmental relocations, trade-ins, and items to be sent to surplus. Capital Assets and the Biomed group will periodically attend the clinical leadership meetings to re-enforce the need to communicate any devices status changes.

Responsible Party

Gene Chandler, Director of Integration, McGovern Medical School
Heidemarie Hellriegel, Assistant Director of Capital Assets Management
Saeed Chaudhry, Vice President, Executive Director Operations - UTP

Implementation Date

March 11, 2022

We would like to thank the UTP Operations, Physician Business Services, Capital Assets Management, and Epic Operating staff and management who assisted us during our review.



Daniel G. Sherman, MBA, CPA, CIA
Associate Vice President & Chief Audit Officer

NUMBER OF PRIORITY FINDINGS REPORTED TO UT SYSTEM

None.

MAPPING TO AUDITING & ADVISORY SERVICES FY 2020 RISK ASSESSMENT

Reference	Risk	Risk Rating
IT 144	Medical devices are not adequately cleaned and maintained.	High

DATA ANALYTICS UTILIZED

None.

AUDITING & ADVISORY SERVICES ENGAGEMENT TEAM

AVP/CAO - Daniel G. Sherman, MBA, CPA, CIA
Audit Manager - Brook Syers, CPA, CFE, CISA, CIA
Auditor Assigned - Lieu Tran, CISA

END OF FIELDWORK DATE

September 13, 2021

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ISSUE DATE

October 20, 2021

REPORT DISTRIBUTION

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APPENDIX A UT SYSTEM PRIORITY FINDINGS MATRIX

The University of Texas System
Systemwide Internal Audit
Priority Findings Matrix

Priority Findings Matrix	ACRMC Reporting	Institutional Reporting		
	Priority Finding	HIGH	MEDIUM	LOW
QUALITATIVE RISK FACTORS – Potential Probability and Consequences in various risk areas with respect to impact on institution as a whole				
Reputation: Damaged to the image of the institution and/or UT System	High probability that donors and other funding sources will withdraw or withhold funding	High probability that individuals will not choose to participate as students, faculty, or other stakeholders	Medium probability that individual stakeholders will not choose to participate in the institution	Low probability that individual stakeholders will be affected
	National media exposure	Adverse regional media exposure	Adverse local media exposure	No media exposure
Information Security: Integrity, confidentiality and availability of information	High probability of regulatory action or loss of reputation or affect on availability of budget in connection with incorrect external financial reporting	Medium probability of some external financial/operating data being incorrect	Low probability of external financial or operating data being incorrect	N/A
	High probability of data breach	Medium probability of data breach	Low probability of data breach	Opportunity to enhance existing acceptable system
	N/A	High probability of key internal financial/operating data being incorrect	Medium probability of internal data being incorrect	Low probability of internal information being incorrect
Compliance: Compliance with external legal or regulatory requirements	High probability of loss of funding, prosecution, significant financial penalty, negative legal action and/or significant, prolonged adverse impact on institution's	Medium probability of loss of funding, prosecution, significant financial penalty, negative legal action and/or significant, prolonged adverse impact on	Low probability of loss of funding, prosecution, significant financial penalty, negative legal action and/or significant adverse impact on institution's reputation	N/A
	N/A	High probability of increased monitoring or negative perception by the regulators	Medium probability of increased monitoring or negative perception by the regulators	Low probability of increased monitoring or negative perception by the regulators
Accomplishment of Management's Objectives: Goals being met, projects being successful	High probability that a major operating project or initiative (i.e. a new degree program or information system) will be materially late, over budget or technically deficient	Medium probability that an operating project will miss time, cost or technical goals	Low probability that an operating project will not achieve some of its goals	Process improvement opportunity to assist in achieving a goal
	N/A	High probability that an internal activity or project will not achieve its goals	Medium probability that an internal activity or project will not achieve some of its goals	Low probability that an internal activity or project will not achieve some of its goals
Effectiveness and Efficiency: Objectives at risk and/or resources being wasted	High probability of a mission critical activity failing with major regulatory, reporting consequences	Medium probability of a mission critical activity failing with major regulatory, reporting consequences	Low probability of a mission critical activity failing with major regulatory, reporting consequences	N/A
	N/A	High probability that some objectives are not met	Medium probability of some objectives not being met	Low probability that some objectives may not be met
	N/A	High probability of significant cost over runs	Medium probability of significant cost over-runs	Low probability of significant cost over runs
	N/A	High probability of a significant waste of resources	Medium probability of a significant waste of resources	Low probability of a significant waste of resources
Capital Impact: Loss or impairment of use of assets	High probability of significant financial loss of use of assets with reputation consequences	Medium potential for significant financial loss of use of assets with reputation side effects	Low probability for significant financial loss of use of assets with reputation side effects	Probability of immaterial and/or small financial losses of use of assets with minimal reputation
	Loss of control over significant assets	Loss of control over other assets	Minor control deficiency over assets	Opportunity to improve existing controls over assets
Life Safety	High probability for loss of life	Medium probability for loss of life	Low probability for loss of life	N/A
	N/A	High probability for personal injury	Medium probability for personal injury	Low probability for personal injury
	High probability of material release of toxics/infectious disease	Medium probability for: release of toxics/infectious disease	Low probability for release of toxics/infectious disease	N/A
	High probability of Substantial incident of toxics/infectious disease effects	Medium probability of toxic/infectious disease effects	Low probability of toxic/infectious disease effects	N/A

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The University of Texas System
Systemwide Internal Audit
Priority Findings Matrix

Priority Findings Matrix	ACRMC Reporting	Institutional Reporting		
	Priority Finding	HIGH	MEDIUM	LOW
OPERATIONAL CONTROL RISK FACTORS - Vulnerabilities in operational controls with consequences of not achieving objectives (If strategy or important operational objectives are directly impacted):				
<i>Operational Oversight/Alignment</i>	Operational oversight, alignment or management issue has the capacity to derail or significantly impact an Institutional or UT System strategic initiative	Operational oversight, alignment or management issue has the capacity to impair progress on an Institutional strategic initiative	N/A	N/A
<i>Management Oversight</i>	Management oversight control of critical organizational objectives is absent	Management oversight control of critical organizational objectives is ad hoc and/or not formalized	Management oversight control of critical organizational objectives is weak in important areas	Management oversight control of critical objectives can be improved
<i>Management Alignment</i>	Management's alignment of people, process and technology to efficiently accomplish organizational objectives is lacking risk awareness creating critical inefficiency and risk exposure	Management's alignment of people, process and technology to efficiently accomplish organizational objectives is not effectively creating awareness of inefficiencies and potentially significant risks, potentially impacting objective achievement	Key organizational components (trained people, defined process, or appropriate technology) are exposed to moderate risks yet to be addressed, potentially impacting objective achievement	Key organizational components (trained people, defined process, or appropriate technology) are exposed to low risks yet to be addressed, potentially impacting objective achievement
<i>Designed Controls</i>	Designed controls within objective critical operations are inadequate or are non-functional impacting objective achievement	Designed controls within important operations are not functional on a consistent day-to-day basis, with no compensating controls, potentially impacting objective achievement	Designed controls within important processes and transactions are inconsistent in their effectiveness, with no compensating controls, potentially impacting objective achievement	Breakdown of designed controls on a frequent and regular basis with compensating controls, but little impact on the achievement of objectives
	N/A	Control or process improvement opportunities that will provide a measurable economic result (significant to the institution)	Control or process improvement opportunities that will correct a reputational or compliance deficiency	N/A
QUANTITATIVE RISK FACTORS – Estimated Financial Consequences with respect to impact on the institution as a whole (quantitative factors % will vary by institution, so may be agreed upon by the institutional Chief Audit Executive & Chief Business Officer)				
<i>Payments (including fines and legal costs)</i>	>5% of outlays/expenditures	>2% to 5% of outlays/expenditures	1% to 2% of outlays/expenditures	<1% of outlays/expenditures
<i>Lost Revenues (actual and/or opportunities)</i>	>5% of Revenue	>2% to 5% of Revenue	1% to 2% of Revenue	<1% of Revenue